In The United States Court of Appeals
For the Sixth Circuit

In re: State of Ohio Board of Pharmacy, Petitioner. [County of Lake, Ohio, et al. v. Purdue Pharma, L.P, et al] [The County of Trumbull, Ohio v. Purdue Pharma et al.] {Relates to: National Prescription Opiate Litigation}	Case No. _____ United States District Court for the Northern District of Ohio, Eastern Division. [MDL No. 2804; Case No. 18-op-45032 and 18-op-45079]

PETITION FOR A WRIT OF MANDAMUS TO THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO AND MOTION FOR STAY OF DISTRICT COURT ORDER PENDING MANDAMUS

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I. Introduction and Summary of Argument

The State of Ohio Board of Pharmacy ("the Board") is seeking a writ of mandamus under 28 U.S.C. § 1651 and F.R.A.P. 21 holding that the Northern District of Ohio ("the district court") abused its discretion in requiring the Board to disclose confidential information found in the Ohio Automated Rx Reporting System ("OARRS") containing the sensitive health information of over seven million Ohioans and in failing to certify the issues for appeal. The Board also respectfully requests that this Court promptly stay the district court's order compelling the Board to turn over OARRS data pending disposition of this petition.

OARRS is a database operated by the Board that allows prescribers and pharmacies to monitor the dispensing of controlled substances to their patients for suspected abuse or diversion (i.e., channeling drugs into illegal use). For over the last decade, pharmacists around the state have entered confidential and privileged information about their dispensation of controlled substances to Ohio citizens into OARRS. In the underlying case, the district court has ordered the Board to essentially produce the entire OARRS database to third parties who are unauthorized by law to receive such data which includes disclosure of the sensitive health information of over seven million Ohioans. The specific information the district court has directed the Board to produce would provide the means to unlock the identity of millions of people's prescribing history.

The Board has made repeated and strenuous objections that the OARRS data is confidential and privileged pursuant to both Ohio and federal law[1] and therefore should not be disclosed. These arguments have been rejected by the district court. Based upon the broad scope and seriousness in ordering this disclosure, the Board is entitled to request a review from this Court of the district court's order. In the same entry ordering the disclosure of the OARRS data, the district court also *sua sponte* denied the Board the right to appeal the district court's order. Thus, in order to protect the confidential and privileged OARRS data, the Board's only recourse was to pursue this mandamus action.

A party seeking mandamus must demonstrate that it has a "clear and indisputable" right, there are "no other adequate means" of relief, and the writ is otherwise "appropriate under the circumstances." *Cheney v. United States Dist. Court D.C.*, 542 U.S. 367, 380-81 (2004). The district court left the Board with "no other adequate means" of relief when it refused to certify the issue for appeal under 28 U.S.C. §1292. Without the right to appeal, the Board has no relief to seek review of the district court's abuse of discretion in ordering the disclosure of the confidential

[1] The data that is contained in OARRS is expressly confidential under state law – specifically O.R.C. 4729.80 and 4729.86. The Board is only authorized to release OARRS information for certain limited reasons and Ohio law expressly prohibits the use of OARRS information in civil cases. There appears to be no dispute that this discovery issue turns on interpreting this rule because the case before the district court was solely premised on Ohio nuisance law.

and privileged information. A review of the underlying district court's order is "appropriate under the circumstances" as this involves the disclosure of sensitive health information of millions of Ohio citizens. This is just one "track" of claims by nearly 2,000 political subdivisions that have been consolidated in the district court as multi-district litigation ("MDL"). The district court order will be setting important - and arguably improper - precedent that will not only affect the other pending MDL matters in Ohio, but the similar pending national cases as well. The Board is entitled to a writ of mandamus and a stay until this Court reviews the district court's order.

II. Statement of Facts

The OARRS Program and its Strict Limitations.

OARRS records are highly confidential, and the Board tightly controls access. *See* Acceptable Use Policies at https://www.ohiopmp.gov/Documents.aspx. The confidentiality and security of data is central to the operation of all prescription drug monitoring programs ("PDMP"). *See Whalen v. Roe*, 429 U.S. 589, 600-602 (1977). OARRS includes a patient database which contains records of all controlled substances dispensed to outpatients. The patient database has a portal limited only to an authorized user, which is intended to be used by both law enforcement and other statutorily-designated categories of users to ensure compliance with Ohio law. *See* https://www.ohiopmp.gov/. In a typical patient database transaction, a patient

presents a prescription for a controlled substance to a licensed pharmacist in the state of Ohio. After dispensing that medication, the pharmacist logs the following information into OARRS pursuant to Ohio Administrative Code 4729:8-3-02:

1. Pharmacy drug enforcement administration registration number
2. Pharmacy name
3. Pharmacy address
4. Pharmacy telephone Number
5. Patient full name
6. Patient residential address
7. Patient telephone
8. Number Patient date of birth
9. Patient gender
10. Prescriber's full name (first name and last name)
11. Prescriber's drug enforcement administration registration number
12. Date prescription was issued by the prescriber
13. Date the prescription was dispensed or sold by the pharmacy
14. Indication of whether the prescription dispensed is new or a refill
15. Number of the refill being dispensed
16. Nation drug code of the drug dispensed
17. Number of refills authorized by the prescriber
18. Quantity of the drug dispensed
19. Number of days' supply of the drug dispensed
20. Serial or prescription number assigned to the prescription order
21. Source of payment for the prescription
22. Pharmacy national provider identification (NPI) number
23. Prescriber's national provider identification (NPI) number
24. ICD-10-CM or CDT diagnosis/procedure code

Access to the patient database is tightly controlled. Limited access is granted to pre-approved individuals for specific authorized purposes; the scope of access is

limited to only that information which would be appropriate for the particular user to access. *See* O.R.C. 4729.80(A). In the case of law enforcement officials, for instance, authorization to access an individual's OARRS data is only granted after entry of a case number and approval for access by their supervisor. *See* Ohio Administrative Code 4729-37-08(B); *State v. Meyers*, 12th Dist. App. No. CA2014-02-002, 2015-Ohio-160, 27 N.E.3d 895, ¶ 13. Even then, the official would only have access to the records necessary to complete that particular investigation.

The same access restrictions are true of any other type of user. Each user may access only the information necessary to perform their official duties. For instance, among those granted access are health care professionals who prescribe reportable medications and pharmacists who dispense those medications. The physicians may only access those records directly related to patients presently under their care or to their own prescribing. O.R.C. 4729.80(A)(5). When the Board discovers abuse or misuse of the database, it both refers violators for criminal prosecution and revokes or restricts access for egregious abuses of the database. Improper access to, or use or distribution of, information contained within the OARRS database can be punishable by a felony. *See* O.R.C. 4729.99(J); *Meyers*, 27 N.E.3d at 899.

The Board Provided A "Research Extraction" to the Pharmacy Defendants.

Previously in the MDL, the Board provided a "research extraction" of the OARRS data to McKesson – one of the defendants that settled. Permitted by O.R.C.

4729.80(C), the OARRS data provided to McKesson was de-identified and did not provide pharmacy names and addresses, physician's names and contact information, or any patient identifying information. This "research extraction" has been shared within the MDL with other defendants. Earlier in the MDL, the Board came before this Court on a mandamus that was granted but was subsequently determined to be moot. *See In re: State of Ohio Board of Pharmacy*, Case No. 20-3375.

The research extraction included many of the database fields. And for some of the fields, a randomized "hash" was given to each individual patient, along with separate "hash" fields for prescriber names and pharmacy names. Here is a single entry of the research extraction provided to the Defendants:[2]

DateFilled	01/01/2015
RxNumber	123456
RefillCode	0
Quantity	30
DaysSupp	30
NDC	54092038101
Drug	ADDERALL XR 5 MG CER
TherClassCode	2820040010
TherClassDesc	Amphetamine & Comb.
DateWritten	01/01/2015
NumOfRefillsAuth	0
PaymentType	4

[2] This is based on an actual prescription. Out of an abundance of caution, counsel has randomized the date the prescription was written and filled, the RX number, the zip code, and for the unique identifiers, changed any numbers to a 1 and any letters to an A. The extraction provides the first three numbers of a zip code. The research extraction provided information for all available fields the Pharmacy Defendants requested, although some of the fields were provided in de-identified fashion.

PharmacyHash	1111AAAAA11AA1111A11AA1AA11AA1111AAAAA
PharmacyZip	445
PharmacyBACCode	A
PharmacyBACSubCode	3
PrescriberHash	1AA11AA111A1111AA111111AA11A111111AA111A1
PrescriberZip	445
PrescriberBACCode	C
PrescriberBACSubCode	
PrescriberSpecialty	Pediatric medicine
PatientGroupIDHash	A1A1111A11111A11AAAAAAA1AA11111A11111A11A1
PatientAge	8
PatientSex	2
PatientZip	445

Using the unique "hash" for each patient, the Pharmacy Defendants can sort the entire database by patient. This "hash" will be identical for a specific patient for all of that patient's transactions in the database. Thus, the Pharmacy Defendants can identify every prescription filled for a specific patient that is stored in OARRS – but they would not know the name of the patient. The Pharmacy Defendants could do the same for the pharmacies and prescribers – again, without knowing their name, as there is also a hash assigned to each pharmacy and prescriber.

III. Statement of the Case

A. Procedural History

Manufacturers and distributors of opioids are currently defending against a broad range of lawsuits brought by numerous public entities. Claims by nearly 2,000

political subdivisions have been consolidated in the U.S. District Court for the Northern District of Ohio as the MDL matters. This mandamus relates to "Track Three Cases" that involve Lake and Trumbull Counties in Northeast Ohio.

In June 2020, a number of large pharmacy companies[3] that operate in Northeast Ohio served a subpoena on the Board requesting the names and addresses of the pharmacies and prescribers.[4] A true and accurate copy of the Subpoena is attach as Exhibit "A." Upon receipt of the subpoena, the Board communicated with the Pharmacy Defendants that it would not be responding to the subpoena for the same reasons that were argued at length in the earlier MDL motions and mandamus action.[5] The Board and the Pharmacy Defendants agreed to a procedure involving the Pharmacy Defendants filing a Motion to Compel.

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[3] The defendants at issue are CVS Rx Services, Inc. CVS Indiana, LLC, CVS Pharmacy Inc. and Ohio CVS Stores, LLC, Rite Aid of Maryland, Inc. Rite Aid Hdqtrs. Corp., Walgreen Co., Walgreen Eastern Co., HBC Service Company, Giant Eagle, Inc., Discount Drug Mart, and Walmart Inc. For the purposes of this filing, they will collectively be known as the "Pharmacy Defendants."

[4] The identity of the pharmacies and prescribers are provided by a unique identifying number but not by actual name.

[5] This is the second time that this issue has been before this Court. In the Track One-B litigation, the Pharmacy Defendants requested the same OARRS data from the Board to defend against a claim that they had improperly dispensed opioids. Judge Polster granted a motion to compel, requiring the Board to turn over OARRS data. The Board filed a petition for a writ of mandamus which quickly became moot. *See In re: State of Ohio Board of Pharmacy*, Case No. 20-3375. In related litigation, this Court held that it had been an abuse of discretion for the district court in the Track One-B cases to allow dispensing claims against the Pharmacy Defendants. *In re Nat'l Prescription Opiate Litig.,* 956 F.3d 838 (6th Cir. 2020). In light of that order,

On July 1, 2020, the Pharmacy Defendants filed a motion to compel against the Board to produce the identifying materials from the OARRS database requested in their subpoena. A true and accurate copy of the Motion to Compel (MDL Doc. # 3364) is attached as Exhibit "B." Specifically, the Pharmacy Defendants want to show "widespread alternative causes of the alleged nuisance, e.g., the large number of 'over-prescribers,' 'pill mills,' and other dispensers" and to "identify doctor shoppers." Since the research extraction provided by the Board earlier in the MDL allows the Pharmacy Defendants to do this, the Board rightfully objected to this unnecessary and prohibited production of confidential and privileged data as set forth in the Board's Memorandum in Opposition to the Motion to Compel. A true and accurate copy of the Board's Memorandum in Opposition (MDL Doc. # 3380) is attached as Exhibit "C." Over the Board's objection, the district court granted the motion to compel on July 24, 2020. True and accurate copies of the Pharmacy Defendants' Reply Memorandum (MDL Doc. # 3391) and the district court's order (MDL Doc. # 3395) are attached as Exhibits "D" and "E," respectively.

In granting the motion to compel, the district court incorrectly held that (1) the Pharmacy Defendants have demonstrated their need for the identifying information, (2) there is no likelihood of invasion of patient privacy, and (3) there is

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Judge Polster withdrew the order to turn over OARRS data in the Track One-B litigation.

no privilege that applies to the data. Therefore, the district court directed that the Board must produce the identifying information.

B. The Arguments Before the District Court

The Pharmacy Defendants' subpoena sought the entire, identified, OARRS database. See Exhibit A. Relevant here, the Pharmacy Defendants wanted:

> Prescription data from the Ohio Automated Rx Reporting System ("OARRS") for the following prescription drugs, to the extent available: oxycodone, hydrocodone, hydrophone, fentanyl, oxymorphone, morphine, methadone, and tapentadol, alprazolam, chlordiazepoxide, clobazam, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, triazolam, carisoprodol, cyclobenzaprine, orphenadrine, and tizanidine. For each prescription, identify the drug name, *prescription number*, NDC number, date filled, quantity dispensed, dosage form, days' supply, MME, *prescriber's name*, prescriber's DEA number, dispensing pharmacist, *dispensing pharmacy*, patient's unique identification number, patient's state of residence, number of refills authorized (if any), diagnostic code, method of payment, patient paid amount, whether the prescription was covered by third party payers, and any other fields identified following a meet and confer with counsel for the Pharmacy Defendants.

Exhibit A, p. 11 (emphasis included)[6].

This was almost identical to a subpoena issued by the Pharmacy Defendants in Track One-B cases involving Cuyahoga and Summit Counties. The Pharmacy Defendants and the Board agreed that the normal process of sending objection letters

[6] The emphasized items represent the information the Pharmacy Defendants requested in de-identified fashion and to which the Board objected.

would be superfluous and it would be most appropriate to simply suggest a briefing schedule to the district court. Accordingly, the parties filed their respective motions.

The Pharmacy Defendants expressly stated that they were seeking OARRS data from 2006 onward in order to identify individual patients – albeit in de-identified fashion. "The OARRS data is also necessary to identify 'doctor shoppers.'" Exhibit B, p. 8. The Pharmacy Defendants emphasized that:

> ***OARRS is the only dataset anywhere that allows the tracing of individuals across prescribers and pharmacies.*** Therefore, it is the only dataset that allows the identification of doctor shoppers who sought pills from multiple places, as well as the over-prescribers who wrote those patients' prescriptions. Identifying those patients and prescribers is a primary purpose of OARRS.

Exhibit B, p. 11 (emphasis in original).

In its opposition to the Motion to Compel, the Board objected to the subpoena because the information requested (including the identity of licensees) is confidential and privileged under state and federal law, that the de-identified information in the Pharmacy Defendants' possession is sufficient, and they could easily reverse engineer the database if they received the identifiers for the pharmacies and prescribers in order to identify individual patients. Exhibit C, pp. 5-11.

On July 24, 2020, the district court granted the Pharmacy Defendants' motion to compel. Exhibit E. The district court determined that the Pharmacy Defendants need for the identifying information outweighs any countervailing concerns of the Board related to the identification of the patient and that the information is not

confidential or privileged under state or federal law. Exhibit E, p. 6. Finally, the district court noted that the State of New York had turned over the names of prescribers and pharmacies from its own PDMP, leading it to conclude that "OBOP's concerns about privacy and statutory restrictions are overblown." Exhibit E, p. 6, fn 8. The district court did *not* directly address the Board's argument that O.R.C. 4729.80 makes the identities of licensees in OARRS privileged, nor did it address the Board's argument that the de-identified data already in the Pharmacy Defendants' possession provide the information that the Pharmacy Defendants need.

IV. Argument

A. Standard of Review

An appellate court has the power under 28 U.S.C. § 1651(a) to issue a writ of mandamus directing the conduct of a district court where (1) the petitioner has a "clear and indisputable" right to relief; (2) there are "no other adequate means to attain the relief"; and (3) mandamus relief is otherwise "appropriate under the circumstances." *Cheney v. United States Dist. Court D.C.*, 542 U.S. 367, 380-81 (2004). In short, only "exceptional circumstances amounting to a judicial 'usurpation of power'" or a "clear abuse of discretion" will "justify the invocation of this extraordinary remedy." *Id*. at 380.

In an effort to distinguish between "errors that are merely reversible and not subject to mandamus, and those errors that are of such gravity that mandamus is

proper," this Court balances five factors: (1) whether the petitioner has no other adequate means to obtain the relief he seeks; (2) whether he "will be damaged or prejudiced in a way not correctable on appeal"; (3) whether "the district court's order is clearly erroneous as a matter of law"; (4) whether "the district court's order is an oft-repeated error, or manifests a persistent disregard of the federal rules"; and (5) whether "the district court's order raises new and important problems, or issues of law of first impression." *John B. v. Goetz*, 531 F.3d 448, 457 (6th Cir. 2008). "These factors need not all be met, and some factors will often be balanced in opposition to each other." *Id.* Although the standard for mandamus is, and should be, a high one, it is satisfied in the extraordinary circumstances presented here. Indeed, the first, second, third, and fifth factors all weigh heavily in favor of issuing mandamus.

B. The Board Has No Other Adequate Means to Attain Relief and Will Be Damaged in a Way Not Correctable on Appeal.

It is well established that a party will satisfy the first two elements of mandamus when it is appealing a court order requiring the disclosure of confidential or privileged information. This Court has held that "mandamus may be used as a 'means of immediate appellate review of orders compelling the disclosure of documents and information claimed to be protected from disclosure by privilege or other interests in confidentiality.'" *John B.*, 531 F.3d at 457 (6th Cir. 2008) (quoting *United States ex rel. Pogue v. Diabetes Treatment Centers of Am., Inc.*, 444 F.3d 462, 472 (6th Cir. 2006)).

This is a classic example. The Board is *not* a party to the litigation – it is involved solely because the Pharmacy Defendants are seeking discovery from it. The Board cannot seek an immediate appeal under the "collateral order" doctrine under 28 U.S.C. §1291. *Mohawk Indus. v. Carpenter*, 558 U.S. 100, 103 (2009). "Mandamus must issue or [the Board] will be obliged to obey the binding court order[.]" *In re Lott*, 424 F.3d 446, 450 (6th Cir. 2005). If this Court does not halt the order to produce OARRS data, then the damage will be done and the confidentiality of the OARRS data will already have been lost. There will be no way for the Board to appeal once final judgment has been issued.

Moreover, the protective order issued in the district court does not guarantee the OARRS data will remain confidential. This Court has repeatedly held that the existence of a confidentiality agreement or protective order will not necessarily protect the data from being publicly available as a court record. Courts distinguish between limiting public disclosure of information during discovery versus the adjudicative stage of a case. *See Shane Grp., Inc. v. Blue Cross Blue Shield of Mich.*, 825 F.3d 299, 305 (6th Cir. 2016). "The line between these two stages, discovery and adjudicative, is crossed when the parties place material in the court record." *Id.* (citing *Baxter Int'l, Inc. v. Abbott Labs.*, 297 F.3d 544, 545 (7th Cir. 2002)). "Unlike information merely exchanged between the parties, '[t]he public has a strong interest in obtaining the information contained in the court record.'" *Shane Grp.*, 825 F.3d

at 305 (quoting *Brown & Williamson Tobacco Corp. v. F.T.C.*, 710 F.2d 1165, 1180 (6th Cir. 1983)). Thus, a party seeking to have its confidential information filed under seal has a "heavy" burden of overcoming a "'strong presumption in favor of openness' as to court records." *Shane Grp.*, 825 F.3d at 305 (quoting *Brown & Williamson*, 710 F.2d at 1179) (explaining that only "the most compelling reasons can justify non-disclosure of judicial records" (citation and quotations omitted)).

Last year, this Court discussed the presumption in favor of openness of court records in a companion case, explaining:

> The presumption in favor of openness of court records is justified because "[t]he public has an interest in ascertaining what evidence and records the District Court and this Court have relied upon in reaching our decisions." [Citations omitted]. This strong presumption in favor of openness is only overcome if a party "can show a compelling reason why certain documents or portions thereof should be sealed, [and] the seal itself [is] narrowly tailored to serve that reason." [Citations omitted]. Further, "the greater the public interest in the litigation's subject matter, the greater the showing necessary to overcome the presumption of access." [Citations omitted].

In re Nat'l Prescription Opiate Litig., 927 F.3d 919, 939 (6th Cir.2019) (emphasis added) (quoting *Shane Group, Inc. v. Blue Cross Blue Shield of Mich.*, 825 F.3d 299, 305 (6th Cir.2016)). This Court concluded "[w]e therefore vacate any district court orders to the extent they permit sealing or redacting of court records." *Id.* at 939. Thus, the mere existence of a protective order is not sufficient to protect the OARRS data from possibly becoming accessible as a publicly available court record.

C. The District Court's Failure to Certify This Case for Immediate Appeal Under 28 U.S.C. §1292(b) Was Erroneous as a Matter of Law.

While discovery orders are generally not considered final for purposes of 28 U.S.C. § 1291, "this Court has authority to issue a writ of mandamus under the All Writs Act, 28 U.S.C. § 1651" where "there is extraordinary need for review of an order before final judgment and the District Court has refused to certify the issue pursuant to § 1292(b)[.]" *In re Lott*, 424 F.3d at 449. Even if the district court did not agree with the Board's arguments it should have at least permitted the Board to appeal this critical confidentiality issue under 28 U.S.C. §1292 which states:

> (b) When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order. The Court of Appeals which would have jurisdiction of an appeal of such action may thereupon, in its discretion, permit an appeal to be taken from such order, if application is made to it within ten days after the entry of the order . . . .

28 U.S.C. §1292(b).

This Court has established that the "three factors that justify interlocutory appeal should be treated as *guiding criteria* rather than *jurisdictional requisites*." *In re Trump*, 874 F.3d 948, 951 (6th Cir. 2017) (quoting 16 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure §3930 (3d ed. 2002)) (emphasis in original). However, if a court finds that all three factors are present, a court has a

"duty . . . to allow an immediate appeal to be taken." *Ahrenholz v. Board of Trustees*, 219 F.3d 674, 677 (7th Cir. 2000). *See also In re Trump*, 928 F.3d 360, 369 (4th Cir. 2019) (same).

1. The District Court's Order Involves a Controlling Question of Law.

There is a clear controlling issue of law here. Under O.R.C. 4729.80, OARRS data (including the identity of licensees) is confidential and the Board is permitted to release information from OARRS only under several specific circumstances. It appears to be uncontested that the request here does not satisfy any of those specific circumstances. O.R.C. 4729.86(B) provides that "A person shall not use information obtained pursuant to division (A) of section 4729.80 of the Revised Code as evidence in any civil or administrative proceeding." The controlling question of law is whether reading those two provisions together establishes that there is a privilege – notwithstanding the fact that the statutes do not use that specific term.

2. There are Substantial Grounds for Difference of Opinion about the Controlling Issue of Law.

This Circuit has adopted the legal standards of the Ninth Circuit for determining whether there is a substantial ground for difference of opinion. *In re Trump*, 874 F.3d 948, 952 (6th Cir. 2017). The question is whether "reasonable jurists might disagree on an issue's resolution, not merely where they have already disagreed." *Id*. (quoting *Reese v. BP Exploration, Inc*., 643 F.3d 681, 688 (9th Cir.

2011). So a "novel issue may be certified for interlocutory appeal without first awaiting development of contradictory precedent." *Id*. (quoting *Reese*, 643 F.3d at 688). Here, a reasonable jurist could conclude that Ohio law bars the disclosure of the OARRS data.

Under O.R.C. 4729.80, the Board is permitted to release information only under several specific circumstances. While there is a provision that authorizes the Board to comply with a court order "in connection with the investigation or prosecution of a possible or alleged criminal offense" (O.R.C. 4729.80(A)(4)) and a provision for responding to grand jury subpoenas (O.R.C. 4729.80(A)(3)), there is no provision for such disclosure in a civil case.

Ohio law regarding the admissibility of OARRS information in civil cases cannot be clearer: "A person shall not use information obtained pursuant to division (A) of section 4729.80 of the Revised Code as evidence in any civil or administrative proceeding." O.R.C. 4729.86(B). Under O.R.C. 4729.86(A)(1), it is unlawful to improperly disseminate information from the OARRS database except for the limited exceptions listed in O.R.C. 4729.80(A) and (B). Improper disclosure of OARRS data is a criminal offense under O.R.C. 4729.99. There is no grant of immunity nor protection that can be afforded to the Board's Executive Director or

Director of the OARRS database for disclosing OARRS content other than for express purposes set forth in the governing confidentiality statutes.[7]

The district court's order expressly requires the Board to disclose the names of pharmacies and prescribers. This order flatly contradicts an Ohio statute which expressly prohibits the Board from releasing information which will "identify a person, ***including any licensee*** or registrant of the board or other entity[.]" O.R.C. 4729.80(C) (emphasis added). The Board licenses Ohio pharmacies. *See* O.R.C. 4729.01(Q) (definition of terminal distributor of dangerous drugs includes pharmacies) and 4729.54 (terminal distributors must obtain a license). Individuals who prescribe controlled medications are licensed by various entities including the State of Ohio Medical Board (O.R.C. 4731.09 and 4730.10), the Ohio Board of Nursing (O.R.C. 4723.41), the Ohio State Dental Board (O.R.C. 4715.10), and the Veterinary Medical Licensing Board (O.R.C. 4741.11).

In its Order granting the Pharmacy Defendants' Motion to Compel, the district court cited a number of cases where courts held statutes designating information as "confidential" is not the same as creating an evidentiary "privilege." Exhibit E, pp.

[7] The Ohio Supreme Court has held that "a third party can be held liable for inducing the unauthorized, unprivileged disclosure of nonpublic medical information" and that "it is for the patient—not some medical practitioner, lawyer, or court—to determine what the patient's interests are with regard to personal confidential medical information." *Biddle v. Warren Gen. Hosp.*, 86 Ohio St.3d 395, 408, 715 N.E.2d 518, 528 (1999).

7-8. The district court added that if the Ohio "General Assembly ***intended to create an evidentiary privilege***, it easily could have done so in express terms." Exhibit E, p. 8 (emphasis added). However, the district court ignored the language in O.R.C. 4729.80 and 4729.86(B), which distinguishes this matter from the cases on which the district court relied. Through those statutes, the Ohio General Assembly not only expressly provided that the OARRS data is confidential, it also, "in express terms," provided that the data cannot be used "as ***evidence*** in any civil or administrative proceeding." O.R.C. 4729.86(B) (emphasis added). Thus, despite the district court's finding to the contrary, the Ohio General Assembly did indeed intend to "create an evidentiary privilege" by expressly stating the OARRS data could not be used as evidence. The fact the statute does not actually use the phrase "privilege" is of no consequence. Based on the foregoing, the second element of §1292(b) is present.

3. The Disclosure of OARRS Data Involves a New Legal Issue and is of Special Consequence.

The United States Supreme Court has implicitly established that the third factor under §1292(b) is met when an entity is raising a privilege claim that either involves a "new legal issue" or is "of special consequence."

> The preconditions for §1292(b) review -- "a controlling question of law," the prompt resolution of which "may materially advance the ultimate termination of the litigation" -- are most likely to be satisfied when a privilege ruling involves a new legal question or is of special

> consequence, and district courts should not hesitate to certify an interlocutory appeal in such cases.

Mohawk Indus., 558 U.S. at 110-111.

The issue about OARRS and whether the OARRS confidential data is privileged is both a novel legal issue and a matter of special consequence. While the issues about the application of Fed. Evid. R. 501 are not novel, the actual application of that rule to O.R.C. 4729.80 and 4729.86 as it relates to a determination of privilege is completely new. No federal courts have required the Board to turn over information from the OARRS database in a federal civil proceeding.

The matter is also of special consequence. Revealing the unique identifying numbers for each and every pharmacy and prescriber to the Pharmacy Defendants would not only be a violation of Ohio's confidentiality protections for licensees, which are expressly identified in the confidentiality codes, it would also be tantamount to providing the Pharmacy Defendants with the unique identifying numbers of individual patients for well over half of all Ohioans.

The breadth of information that is contained in the OARRS database cannot be overstated. This is not the private medical information for a single patient – or even every patient who saw a single doctor. These are the private medical records of over seven million people. The information would permit the Pharmacy Defendants to unlock the identity of millions of people's prescribing history. The Pharmacy Defendants did not dispute that this information could be used in this

fashion and the district court did not disagree. Instead, the district court stated that the Pharmacy Defendants (who had asked for the data, in part, to identify "doctor shoppers") would not be permitted to reverse engineer the data.[8]

Notably, the district court did not place any limits at all in its order as it relates to pharmacies or prescribers. The order is not limited to only a specific time frame, or those that prescribed or dispensed to patients from Northeast Ohio. It also is not limited to prescription opioids. Medicines like testosterone cream, Ambien, Xanax and Ritalin are also controlled substances under Ohio and federal law and are wholly included in the data. These drugs are not part of these lawsuits, but under the court's *carte blanche* order, the Pharmacy Defendants will be able to discover all of that information. Put another way – this is not just any old discovery fight. This is clearly a matter of "special consequence."

D. In the Alternative, the District Court's Order was Clearly Erroneous as a Matter of Law.

This Court also has the option of ruling on the underlying merits because the Board has a clear and indisputable right to relief. The district court erred as a matter of law, when it refused to apply Ohio confidentiality laws without an identification of a specific privilege. Even aside from the statutory prohibition, the district court

[8] Despite the Pharmacy Defendants having been ordered to not, and their assurances that they will not, reverse engineer the data to identify patients, this does not change the fact that it can be done. This precedent should not be set.

abused its discretion in ordering the disclosure of such vast swaths of the OARRS database with insufficient protections.

1. The District Court Abused Its Discretion In Failing To Find That Ohio Law Makes This Information Privileged.

Although the district court held that the Board "is generally correct regarding application of state law privileges in federal cases based on diversity jurisdiction" it failed to apply those to this matter because it found that the Board failed to "show [that] a specific state law privilege exists that governs this precise issue." Exhibit E, p. 7. This Court's binding precedent establishes that under Fed. R. Evid 501, federal courts apply a state's confidentiality laws if the case is being heard under diversity jurisdiction. *See Jewell v. Holzer Hosp. Found., Inc.*, 899 F.2d 1507, 1513 (6th Cir. 1990); *Jaffee v. Redmond*, 518 U.S. 1, 15 (1996). The Track Three case is proceeding solely under a common law claim of nuisance under Ohio law.

As noted above, the district court ordered the Board to provide the identities of pharmacies and prescribers in the OARRS database. But Ohio law forbids the Board from releasing information in the OARRS database about "any person" – including licensees, which is information the district court ordered the Board to produce. Unless one of the exceptions of O.R.C. 4729.80(A) or (B) apply, the Board is simply not permitted to release information from OARRS that will "identify a person, including any licensee or registrant of the board or other entity[.]" O.R.C.

4729.80(C). That includes pharmacies (who are licensed by the Board) and prescribers (who are licensed by an "other entity"). And while OARRS data can be provided in a criminal case under O.R.C. 4729.80(A)(3) and (4), there is no comparable provision for civil cases.[9] On the contrary, "A person shall not use information obtained pursuant to division (A) of section 4729.80 of the Revised Code as evidence in any civil or administrative proceeding." O.R.C. 4729.86(B).

But the order goes further than just the names of pharmacies and prescribers. Here, the district court ordered the Board to provide the Pharmacy Defendants with all the tools they would need to easily determine patients' identities. The Pharmacy Defendants are the biggest pharmacy chains in Northeast Ohio. They have extensive databases detailing what medications they have dispensed to patients. Providing them with the identity of all prescribers and pharmacies for each prescription listed in the research extraction (which the Defendants already have received) will essentially provide the Pharmacy Defendants the identities of countless patients in the OARRS database with only a modicum of reverse engineering.

For example, if Walgreens (one of the Defendants) was supplied with all information for a particular prescription that was filled at a Walgreens pharmacy – the prescription number, drug prescribed, the date the prescription was written, the

[9] Notably, even for criminal cases, there is not carte blanche for broad swaths of the database. O.R.C. 4729.80(A)(3) is limited to searches "relating to the person who is the subject of an investigation being conducted by the grand jury."

date the prescription was filled, quantity, number of refills, prescriber name, and specific pharmacy name and address at which the prescription was filled – Walgreens could easily locate that particular prescription within its records. Walgreens' records would necessarily include the patient name for the prescription, thus, revealing the identity of that patient. Walgreens would then know the unique identifying number for that patient.

Walgreens would then be able to search the database by that patient's unique identifying number to discover every single purchase that patient ever made at *any* pharmacy (not just Walgreens) even years before or years after that patient was a Walgreens customer. The district court addressed these concerns by simply stating in its order that the Pharmacy Defendants would be forbidden from reverse engineering the information. But if the data can be used to "identify a person" then it is barred from disclosure by O.R.C. 4729.80(C), even if the Pharmacy Defendants promise that they won't peek behind the curtain (notably, they expressly asked for the data in order to identify which patients are "doctor shoppers").

Further, if the Pharmacy Defendants intend on using the information obtained from OARRS to support their defense at trial or in dispositive motions, the information would become a court record. As previously discussed, documents and information used to support a claim or defense will likely be publicly accessible as a court record. *See*, *In re Nat'l Prescription Opiate Litig.*, 927 F.3d 919, 939 (6th

Cir.2019). Instead of evaluating Ohio's confidentiality laws, the district court concluded that the Board's "concerns about privacy and statutory restrictions are overblown" because the State of New York provided analogous data voluntarily. Exhibit E, p. 6, footnote 8. The Board has *never* claimed that Ohio's statutes would apply to the State of New York.[10] New York's decision to voluntarily produce its own information is indicative of nothing and certainly cannot be used as the basis for compelling an Ohio agency to produce information in violation of state law.

In the end, the district court abused its discretion in granting the motion to compel production from the OARRS database.

2. The Pharmacy Defendants Already Have the Information In De-identified Format.

The district court also abused its discretion by holding that the Pharmacy Defendants have demonstrated their need for the identifying information and there is no likelihood of invasion of patient privacy. The district court in this case emphasized that it believes that the Pharmacy Defendants will not need the names of individual patients in order to present their case because they can "utiliz[e] OBOP's de-identified patient ID number." Exhibit E, p. 5. Yet, the district court

[10] Although New York's confidentiality statute, 10 NYCRR 80.107 is similar in some respects to O.R.C. 4729.80, Ohio's statute is much more detailed. Most importantly, as discussed repeatedly above, O.R.C. 4729.86(B) specifically prohibits the use of OARRS data in a civil proceeding. The Board is unaware of any similar prohibition in New York law.

held that the Pharmacy Defendants "cannot pursue a potential defense without actual identities [of the pharmacists and prescribers] contained in the OARRS data fields they seek" and that "the relevance for the data is clear." Exhibit E, pp. 4, 6.

Neither the Pharmacy Defendants nor the district court explained why using the de-identified pharmacy ID numbers and prescriber ID numbers in the research extraction is insufficient. The only thing that the Pharmacy Defendants will not specifically know will be the name of the actual prescriber or pharmacy. They still have the ability to use the unique identifiers to identify problematic prescribing or dispensing habits to use as their defense. If the Pharmacy Defendants' "aim" is to "identify alternative causes of the alleged nuisance," the Pharmacy Defendants do not need the specific identities of prescribers – just as they do not need the specific identities of patients to uncover "doctor shoppers." To accomplish their aim, the Pharmacy Defendants can examine prescribing habits of prescribers by their unique number to demonstrate there are prescribers who are over prescribing opioids. For example, if prescriber number "2020" has a history of prescribing opioids in significantly greater numbers than other prescribers, the Pharmacy Defendants can point to prescriber "2020" and any other prescribers with a similar history as an "alternative cause" of the "alleged nuisance." The Pharmacy Defendants have not explained how having the actual name of the prescriber will bolster their defense.

In addition to already being able to identify prescribers and pharmacies with a unique hash, the Board annually produces data detailing doctor shopper statistics in its reports. Those documents were requested and produced as part of the same subpoena at issue here. Moreover, those documents are readily available on the Board's website and are a viable alternative should the Pharmacy Defendants seek to use information pertaining to doctor shoppers in its case, see for example https://www.ohiopmp.gov/documents/Annual%20Report%20(2018).pdf.[11]

E. The District Court's Order Raises New and Important Problems.

As discussed in more detail above, the scope of the discovery being required is immense; it will require the disclosure of information about prescriptions filled for over seven million people. At the risk of repetition – if this order does not "raise new and important problems," it is difficult to imagine any discovery order that does. The fifth factor of mandamus strongly weighs in the Board's favor.

V. This Court Should Stay Enforcement of the District Court Order to Compel Production.

Under Fed. R. App. Proc. 8(a)(2), this Court has discretion to grant a stay or injunction. This Court reviews four factors: (1) whether a party has made a strong showing that it is likely to succeed on the merits; (2) whether it "will be irreparably injured absent a stay;" (3) "whether issuance of the stay will substantially injure the

[11] A copy of the document from this link is attached as Exhibit "F."

other parties interested in the proceeding;" and (4) "where the public interest lies." *Nken v. Holder*, 556 U.S. 418, 434 (2009) (quoting *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987)). "These factors are not prerequisites that must be met, but are interrelated considerations that must be balanced together." *Michigan Coal. of Radioactive Material Users, Inc. v. Griepentrog*, 945 F.2d 150, 153 (6th Cir. 1991). The first two factors are the most critical. *Nken*, 556 U.S. at 434.

Likelihood of success on the merits.

The Board has made a strong showing that it will prevail on the merits. It has identified binding case law that mandates that district courts apply state confidentiality laws when hearing cases that involve only state law claims. The Ohio laws at issue are clear and unambiguous. At the very least, the district court should have certified this matter under 28 U.S.C. §1292(b) so that it could be reviewed further. The Board has a strong likelihood of success on the merits.

Irreparable harm.

It is well established in this Circuit that the disclosure of privileged information is a form of irreparable harm. If a party "is wrongfully forced to disclose privileged communications, there is no way to cure the harm done to [the party] or to the privilege itself, even if some of the disclosure's consequences could be remedied on direct appeal." *In re Lott*, 424 F.3d 446, 452 (6th Cir.2005). Put another way: "privilege operates to prevent the disclosure itself." *Id.* at 451.

Harm to Third Parties and the Public Interest.

The OARRS data at issue includes medical records for the majority of Ohioans. For normal cases, a court order stating that information will remain private will be sufficient. But this is not just any ordinary case. This is a massive MDL with multiple defendants who have untold numbers of lawyers, experts and consultants – all of whom would be able to peruse the OARRS database with only a small amount of research. And the scope of the documentation makes it different from any typical discovery issue.

Because this is the entire database for millions of Ohioans, the interest of third parties and the public at large would be to grant the stay even if there was only a small chance of success – as opposed to the overwhelming case that the Board is bringing.

VI. Conclusion

For the forgoing reasons, the Board respectfully requests that this Court grant a writ of mandamus against the District Court for the Northern District of Ohio requiring it to deny the Defendants' Motion to compel. Alternatively, this Court should require the district court to certify its granting of Defendants' Motion to Compel for interlocutory appeal. In addition, the Board asks that this Court stay its requirement to comply with the order to compel while this matter is pending.

DAVE YOST,
ATTORNEY GENERAL OF OHIO

By:

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CERTIFICATE OF SERVICE

Service on counsel for all parties in the district court has been accomplished via notice filed through the district court's CM/ECF system attaching a copy of this filing on August 19, 2020.

/s/ Kevin L. Murch
Kevin L. Murch (0066833)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *The County of Lake, Ohio, et al. v. Purdue Pharma L.P., et al.*, Case No. 18-op-45032 *The County of Trumbull, Ohio, et al. v. Purdue Pharma L.P., et al.*, Case No. 18-op-45079	**MDL No. 2804** **Case No. 17-md-2804** **Judge Dan Aaron Polster**

NOTICE OF SERVICE OF SUBPOENAS TO OHIO BOARD OF PHARMACY

Pursuant to the applicable Federal Rules of Civil Procedure, the Court's local rules, this Court's Case Management Orders, and any other applicable law or rule, the Defendants in the above-captioned cases will serve subpoenas commanding testimony and the production of documents on the Ohio Board of Pharmacy.

Please find attached copies of (i) the subpoena for the production of documents, including the attached Schedule A (Requests for Production) and Case Management Order No. 2, and subsequent amendments; and (ii) the subpoena for witness testimony at a deposition, including the attached Schedule A (Topics for Examination).

Exhibit A

Date: June 10, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this 10th day of June, 2020, the foregoing has been served via email on the following:

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Linda Singer, lsinger@motleyrice.com

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/s/ Katherine M. Swift
Katherine M. Swift

Attorney for Walgreen Co. and Walgreen Eastern Co.

AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action

UNITED STATES DISTRICT COURT

for the

Northern District of Ohio

In re: National Prescription Opiate Litigation

Plaintiff

v.

Defendant

Civil Action No. 1:17-md-02804-DAP

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION

To: State of Ohio Board of Pharmacy, 77 South High Street, Columbus, Ohio 43215

(Name of person to whom this subpoena is directed)

☑ *Production:* **YOU ARE COMMANDED** to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: Schedule A

Place:	Date and Time:
BUCKLEY KING 1400 Fifth Third Center, 600 Superior Avenue E Cleveland, OH 44114	06/22/2020 5:00 pm (or at a mutually convenient time and place as agreed by the parties)

☐ *Inspection of Premises:* **YOU ARE COMMANDED** to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 6/10/2020

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

/s/ Kaspar J. Stoffelmayr

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* Pharmacy Defendants, who issues or requests this subpoena, are:

Kaspar J. Stoffelmayr, BARTLIT BECK LLP, 54 West Hubbard St., Chicago, IL 60654, (312) 494-4400 kaspar.stoffelmayr@bartlitbeck.com

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* _____

on *(date)* _____ .

❒ I served the subpoena by delivering a copy to the named person as follows: _____

_____

_____ on *(date)* _____ ; or

❒ I returned the subpoena unexecuted because: _____

_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of $ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

(1) ***For a Trial, Hearing, or Deposition.*** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) ***For Other Discovery.*** A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

For access to subpoena materials, see Fed. R. Civ. P. 45(a) Committee Note (2013).

SCHEDULE A

DEFINITIONS

1. "You" and "Your" refers to the Ohio Board of Pharmacy ("the Board") and all others acting or purporting to act on the Board's behalf, including any Board members, committees, subcommittees, working groups, and joint task forces.

2. "Document" is defined to be synonymous in meaning and equal in scope to the meaning of this term in Fed. R. Civ. P. 34. A draft or non-identical copy is a separate Document within the meaning of this term. In all events, the definition of "Document" shall include "Communication," as defined below.

3. "Communication" means the transmittal of information (in the form of facts, ideas, inquiries, or otherwise) and, with respect to oral Communication, includes any Document evidencing such oral Communication. It includes the transmittal of information by any means, including email, SMS, MMS or other "text" messages, social media messages, shared applications from cell phones, or by any other means. "Communication" also shall include without limitation all originals and copies that are provided by You or to You by others.

4. "Plaintiff" or "Plaintiffs" means the County of Lake, Ohio and/or the County of Trumbull, Ohio including their executive and legislative branches, agencies, offices, departments, divisions, commissions, agents, employees, boards, instrumentalities, vendors, administrators, and other persons or entities acting on the named Plaintiff's behalf or controlled by the named Plaintiff.

5. "National Retail Pharmacies" includes, collectively, CVS Pharmacy, Inc.; CVS Rx Services, Inc.; Ohio CVS Stores, L.L.C.; CVS Indiana, L.L.C.; CVS TN Distribution, L.L.C.; Giant Eagle, Inc. and HBC Service Company; Rite Aid Hdqtrs. Corp.; Rite Aid of Maryland, Inc.; Eckerd Corp. d/b/a Rite Aid Liverpool Distribution Center; Walgreens Boots Alliance, Inc.;

Walgreen Co.; Walgreen Eastern Co.; Walgreens Boots Alliance Inc.; and Walmart Inc. Each of the National Retail Pharmacies may be referred to individually as a "National Retail Pharmacy."

6. "Prescription Opioids" means FDA-approved pain-reducing medications that consist of natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body to produce an analgesic effect, including but not limited to prescription medications containing hydrocodone, oxycodone, fentanyl, and hydromorphone, that may be obtained by patients in Ohio only through prescriptions filled by dispensers duly licensed and regulated by the Board.

7. Unless otherwise indicated, the Requests relate to 1) the State of Ohio generally; and 2) Summit and Cuyahoga counties specifically, including all of their political subdivisions.

INSTRUCTIONS

1. The Requests below seek Documents not previously produced in this MDL subject to any previous subpoena or request. The Pharmacy Defendants remain available to meet and confer on the scope of discovery previously produced by the Board of Pharmacy in this MDL, to the extent such discussions may facilitate the production of the additional discovery requested here.

2. Should You consider any of the Documents requested to be confidential such that they should not be generally disseminated to the public or released to the press, we ask that You designate them as such under the Protective Order in the MDL (copy attached), and the parties will deal with them accordingly.

3. Unless otherwise indicated, these requests cover the entire timeframe for which any of the requested Documents have actually been maintained regardless of any applicable records retention policy.

4. All of the following requests are intended to encompass Documents maintained in electronic or paper form, and "correspondence" or "Communications" include emails, letters or other papers, and memos reflecting oral Communications.

5. As these Documents will be shared with a large number of counsel and parties, we ask that You produce copies of them in electronic or paper form. Please let the undersigned know if there are charges or fees for searching or copying and, if so, also advise whether You will provide an invoice for the cost after production or if prepayment is required.

6. We respectfully note that the production of the requested information is in the public interest and will contribute significantly to the public's understanding of the Board's role in administering and enforcing laws governing the practice of pharmacy and the legal prescribing and dispensing of Prescription Opioids in the state of Ohio, including its role in licensing and regulating Terminal Distributors of Dangerous Drugs ("TDDDs"), pharmacists, pharmacy interns, and wholesale drug distributors, as well as maintaining, monitoring, evaluating, and utilizing the Ohio Automated Rx Reporting System ("OARRS"). We therefore request that this production be given priority and concluded as thoroughly and expeditiously as feasible.

7. Any and all references to TDDDs, pharmacies, pharmacists, pharmacy interns, pharmacy technicians, and other pharmacy employees are not limited to national chain pharmacies and their employees but also specifically include regional, state, or local pharmacies[1] and their employees.

[1] Based on the ARCOS data for pharmacies categorized as "retail" pharmacies as opposed to "chain" pharmacies, regional, state, or local pharmacies include (as examples) but are not limited to: Church Square Pharmacy, Cleveland Clinic, Dave's Supermarket, Center for Families & Children Pharmacy, Ohlinger Drug, Fred Albrecht Grocery, Ritzman Pharmacy, and Klein's Pharmacy. These are exemplars; this is not an exhaustive list.

REQUESTS FOR PRODUCTION

1. Prescription data from the Ohio Automated Rx Reporting System ("OARRS") for the following prescription drugs, to the extent available: oxycodone, hydrocodone, hydromorphone, fentanyl, oxymorphone, morphine, methadone, and tapentadol, alprazolam, chlordiazepoxide, clobazam, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, triazolam, carisoprodol, cyclobenzaprine, orphenadrine, and tizanidine. For each prescription, identify the drug name, prescription number, NDC number, date filled, quantity dispensed, dosage form, days' supply, MME, prescriber's name, prescriber's DEA number, dispensing pharmacist, dispensing pharmacy, patient's unique identification number, patient's state of residence, number of refills authorized (if any), diagnostic code, method of payment, patient paid amount, whether the prescription was covered by third party payers, and any other fields identified following a meet and confer with counsel for the Pharmacy Defendants.

2. Automated monthly reports from OARRS that are received by the Ohio Board of Pharmacy's Compliance and Enforcement division, including but not limited to monthly reports of doctor shoppers and monthly "640 lists" of doctors seeing more than 640 patients per month.

3. All Documents in Your possession, custody, and/or control related to any Healthcare Provider or other individual engaged in diversion and or inappropriate prescribing of Opioids, including Documents related to the following:

- **Adolph Harper Jr.** (OH MD license #35.044503) formerly practicing medicine at 2569 Romig Rd., Akron, Summit County, OH.
- **Brian Heim** (OH MD license #35.071122) formerly practicing medicine at 3562 Ridge Park Drive, Suite A, Akron, Summit County, OH.

- **Syed Jawed Akhtar-Zaidi** (OH MD license #35.068528) formerly practicing medicine at 34055 Solon Rd. 210, Solon, Cuyahoga County, OH.
- **Maged Fouad** (OH MD license #35.092644) formerly practicing medicine at 1934 Niles Cortland Rd. NE, Suite B, Warren, Trumbull County, OH.
- **Jerome Yokiel** (OH MD license #35.059140) formerly practicing medicine at 3755 Orange Pl., Suite 103, Beachwood, Cuyahoga County, OH.
- **Lorenzo Lalli** (OH MD license #35.055703) formerly practicing medicine at 18099 Lorain Ave., Suite 312, Cleveland, Cuyahoga County, OH.
- **Frank Lazzerini** (OH MD license #35.092741) formerly practicing medicine at 7452 Fulton Dr. NW, Massillon, Stark County, OH.
- **Ronald Celeste** (OH MD license #35.066648) formerly practicing medicine at 29099 Health Campus Dr. 370, Westlake, Cuyahoga County, OH.
- **Christopher Stegawski** (OH MD license #35.044751) formerly practicing medicine at 4322 Airway Rd. Dayton, Montgomery County, OH.
- **Guang Yang** (OH MD license #35.088219) formerly practicing medicine at 2215 E Waterloo Rd. Ste 313, Akron, Summit County, OH.
- **James Bressi** (OH MD license #34.004592) formerly practicing medicine at 4302 Allen Rd. Suite 300, Stow, Summit County, OH.

- Healthcare Providers or other individuals engaged in diversion beyond those identified above, including but not limited to, Mark Davis, William Kerek, Katherine Richmond, Clive Sinoff, Juan Hernandez, Tony Lababidi, John Nickels, Charles Njoku, Bin Wang, Michael Tricaso, Syed Ali, Michael Wells, Clayton Seiple, Dmitri Souzadalnitski, Kendrik Bashor, Gregory Gerber, Gregory Ingram, Bruce Feldman, Samuel Nigro, Steve Bernie, Diane Javier, Thomas Craig, Louis Eppinger, Patricia Arnold, Anthony Perry, Elizabeth Davis, James Byrge, Judy Barrows, Brittany Glass, Mathew Taylor, Haitham Azem, Toni Carman, David Ernst, Matthew Evenhouse, Marcellus (Stephen) Gilreath, Aimee (Chappelow) Haber, Ghassan Haddad, William Husel, John Kavlich, Matthew Kellems, Joseph Lydon, Mark McAllister, Jayati Rakhit, Ashis Rakhit, Rakesh Ranjan, George Smirnoff, Kutaiba Tabaa, Margy Temponeras, Herman Weaver, Richard Weil, Troy Balgo, William Bauer, Morris Brown, Freeda Flynn, Gary Frantz, George Griffin, Nileash Jobalia, Thomas Romano, Saad Sakkal, and Paul Yang.

4. All Documents reflecting or referring to complaints, investigations, inquiries, or disciplinary actions related to the refusal or failure of a TDDD, pharmacist, pharmacy intern, pharmacy technician, or other pharmacy employee to dispense Prescription Opioids.

5. All Documents reflecting or relating to complaints, problems, or concerns relating to, or harm resulting from, the refusal or failure of a TDDD, pharmacist, pharmacy intern, pharmacy technician, or other pharmacy employee to dispense Prescription Opioids.

6. All Documents relating to the legitimate need for and/or use of Prescription Opioids, including studies, reports, investigations, or analyses regarding the benefits and/or medical uses of Prescription Opioid medications that were prepared by, received by, or participated in by the Board.

7. All Documents constituting or reflecting guidance, publications, notices, or other Communications from the Board to licensees regarding Prescription Opioids.

8. Board files and records relating to diversion or misuse of Prescription Opioids, including but not limited to the following: (a) correspondence related to potential or actual diversion, overprescribing, or misuse of Prescription Opioids; (b) correspondence from or to the DEA or any other federal agency, any Ohio state officer or agency, or any official of any Ohio county or municipality relating to the diversion, overprescribing, or misuse of Prescription Opioids; (c) complaints made to the Board relating to TDDDs, pharmacists, pharmacy technicians, pharmacy interns, other pharmacy employees, or other entities regulated by the Board relating to diversion, overprescribing, or misuse of Prescription Opioids, and correspondence and other records relating to such complaints; and (d) correspondence and related Documents concerning suspicious activity or concerns raised about pharmacists, pharmacy interns, pharmacy technicians, other pharmacy employees, or other entities regulated by the Board involving Prescription Opioids.

9. All Documents reflecting or describing efforts of any kind (including any processes involving review of OARRS data) by the Board to identify, investigate, and report to other Ohio state agencies, federal agencies, or to federal, state, or local law enforcement any of the following regarding Prescription Opioids in Ohio: (i) overprescribing by doctors or other prescribers; (ii) doctor-shopping or counterfeiting of prescriptions by patients; or (iii) improper

dispensing or failing to dispense Prescription Opioids by TDDDs, pharmacists, pharmacy interns, pharmacy technicians, or other pharmacy employees.

10. All Documents reflecting or relating to enforcement actions (including but not limited to fines, suspensions, revocations, and letters or other formal warnings or notices) taken by You against any licensee relating to the dispensing, failure to dispense, diversion, or misuse of Prescription Opioids.

11. All Documents reflecting or relating to any National Chain Pharmacy's cooperation, assistance, and/or participation in any inspection, audit, investigation, or enforcement action (including but not limited to enforcement actions related to fines, suspensions, revocations, and letters or other formal warnings or notices) taken by You against any licensee relating to the dispensing, failure to dispense, diversion, or misuse of Prescription Opioids.

12. All Documents reflecting or relating to any inspection, audit, or investigation conducted by You of any National Chain Pharmacy, including inspections and audits that did not lead to any further investigation or enforcement action.

13. All Documents reflecting or relating to the Board's licensing and discipline of licensees on a summary basis by year.

14. All Documents reflecting or relating to the Board's policies and procedures and training with respect to inspections, audits and/or investigations of licensees, and summary information of inspections, audits and/or investigations of licensees by year.

15. All Documents relating to the use of OARRS by Plaintiffs and/or any entities or persons affiliated with Plaintiffs, including requests for information and the frequency of logins to OARRS.

16. All Documents constituting, referring, or relating to requests for information made by Plaintiffs to OARRS, including all Documents provided in response to such requests and all Documents relating to actions taken or considered based on the information received.

17. All Documents reflecting or relating to all data analyses, statistical analyses and machine learning tools used by OARRS to analyze prescription data, including but not limited to the 100-500 statistical analyses described by Mr. Chad Garner, Director of OARRS, in his November 14, 2018 deposition.

18. All Documents reflecting or relating to all data analyses, statistical analyses and machine learning tools used by OARRS to analyze wholesale distribution data, including but not limited to excessive purchasing, insufficient dispensing and the identification of suspicious orders.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

County of Lake, Ohio v. Purdue Pharma L.P., et al.,
Case No. 18-op-45032

County of Trumbull, Ohio v. Purdue Pharma, L.P., et al.,
Case No. 18-op-45079

MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster

PHARMACY DEFENDANTS' MOTION TO COMPEL LIMITED ADDITIONAL DATA FROM THE OHIO BOARD OF PHARMACY'S OARRS DATABASE

Exhibit B

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INTRODUCTION

In MDL Track 1B, this Court granted the Pharmacy Defendants'[1] motion to compel the production of limited but critical additional data from the Ohio Board of Pharmacy's Ohio Automated Rx Reporting System ("OARRS"). Dkt. 3168. The Court withdrew that Order as moot following the Sixth Circuit's order to strike the Track 1B plaintiffs' amended complaints adding dispensing claims. But the Court explained that it would likely order the data produced in Track 3, which includes dispensing claims. Dkt. 3313 at 2. The Pharmacy Defendants served a new subpoena seeking the same OARRS data in Track 3. The Board refused to comply.

As in Track 1B, the Pharmacy Defendants' Track 3 Subpoena seeks the identity of the prescribers and of the dispensers associated with prescription data the Board produced in Track 1A. The Subpoena does not seek patient information such as name, address, or date of birth, which the Pharmacy Defendants agree is protected health information of the utmost sensitivity.

The prescriber and dispenser data in question is critical to the Pharmacy Defendants' ability to defend against plaintiffs' dispensing claims. This Court has stated repeatedly that the Pharmacy Defendants are entitled to this data. *See* 12/4/19 Hr'g Tr. 49:1-10 ("[Y]ou can get that data….[The Pharmacy Defendants] can defend the case that way."); 12/27/19 Order on Reconsideration, Dkt. 3055 at 3 ("The Court agrees that third-party discovery of the OARRS database may be helpful and necessary…"); Dkt. 3168 at 7 ("the Pharmacy Defendants' need for the data in this litigation outweighs any countervailing concerns").

[1] "Pharmacy Defendants" are CVS Rx Services, Inc., CVS Indiana, L.L.C., CVS Pharmacy, Inc., CVS TN Distribution, L.L.C., and Ohio CVS Stores, L.L.C. ("CVS"), Rite Aid of Maryland, Inc., Rite Aid of Ohio, Inc., Rite Aid Hdqtrs. Corp., and Eckerd Corp. d/b/a Rite Aid Liverpool Distribution Center ("Rite Aid"), Walgreen Co., Walgreen Eastern Co., and Walgreens Boots Alliance Inc. ("Walgreens"), Giant Eagle, Inc. and HBC Service Company ("Giant Eagle"), and Walmart Inc., Wal-Mart Stores East, LP, WSE Management, LLC, WSE Investment LLC, and Wal-Mart Stores East, Inc. ("Walmart").

Without this data, it is impossible to identify the pharmacy where any prescription in the OARRS database was filled, including the roughly 42 percent of the dispensing market in Track 3 that plaintiffs have not sued, and which, under plaintiffs' litigation theory, may be largely or even entirely responsible for the alleged harms plaintiffs claim due to the filling of improper prescriptions.[2] The absence of such data also makes it impossible to identify the physicians who wrote those prescriptions. The Pharmacy Defendants need dispenser and prescriber information for ***all*** relevant prescriptions in the OARRS database to defend against plaintiffs' claims.

This information is indisputably relevant. It may absolve the Pharmacy Defendants completely. It also is uniquely in the hands of the Board, and there is no burden to producing it. The Board already ***has*** produced it, but with the requested fields anonymized. All the Pharmacy Defendants ask is for the Board to update its production, with the requested fields included. The Court should grant the Pharmacy Defendants' motion, as it did in Track 1B.

BACKGROUND

The Board is charged with regulating the practice of pharmacy and the legal distribution of drugs in Ohio. As part of those duties, the Board has developed and maintains OARRS. OARRS consists of two databases: a patient database that contains records of all controlled substances dispensed to outpatients, and an ARCOS-like database that contains records of shipments of those medications by wholesalers and others. This motion concerns the former.

The OARRS patient database includes a variety of information about all controlled substance prescriptions filled in Ohio. In Track 1A—before plaintiffs amended their complaints to add dispensing claims against the Pharmacy Defendants—McKesson served a subpoena for

[2] This percentage of the market is based on morphine milligram equivalents of prescription opioids received by all dispensers, as reported in the ARCOS data. The ARCOS data says nothing about prescriptions filled by any pharmacy or other dispenser.

all OARRS data, including patient-identifying information that the Pharmacy Defendants do not seek. Initially, the Board refused to comply, citing privacy and confidentiality concerns. McKesson moved to compel. The Court denied McKesson's motion. Following that ruling, however, McKesson and the Board continued to meet and confer, and ultimately, the Board voluntarily produced statewide OARRS data from 2008 to 2018, identifying all of the information listed below, ***except*** pharmacy name and address; pharmacy number; physician name and address; physician number; and patient name, address, and condition.

Data Field	Produced?
Date Prescription Filled	yes
Prescription Number	yes
Date Prescription Written	yes
Quantity	yes
Number of Refills	yes
Number of Days Supply	yes
NDC Code	yes
Payment Type	yes
Pharmacy Name	NO
Pharmacy Address	NO
OBOP Pharmacy Number	NO
OBOP Pharmacy Business Activity Codes and Subcodes	yes
Physician Name	NO
Physician Address	NO
OBOP Physician Number	NO
OBOP Physician Business Activity Codes and Subcodes	yes
Patient Name	NO*
Patient Sex	yes
Patient Address	NO
Patient Age	yes
Patient Condition	NO

* Unique Patient ID number supplied instead

See Dkt. 3168 at 3. In place of patient names, the Board produced data identifying patients by a unique number, allowing the same patient to be followed from prescription to prescription. It is undisputed that the produced OARRS data cannot be used to identify the ***pharmacy*** that filled any prescription or the ***prescriber*** who wrote any prescription.

When the Board produced this data, the only claims pending against the Pharmacy Defendants related to their distribution of prescription opioids to their own stores, not their dispensing practices. On November 20, 2019, following the workup for trial of the distribution claims, the empaneling of a jury, and the eve-of-trial settlement of all but one of the remaining non-severed defendants in Track 1, the Court allowed plaintiffs to amend their complaints to add dispensing claims. The Court then granted the Pharmacy Defendants' motion to compel additional OARRS data, concluding the data was necessary to the new dispensing claims. Dkt. 3168. On April 15, the Sixth Circuit ruled that the Track 1 plaintiffs' amendments should not have been allowed, and this Court struck the dispensing claims from Track 1. The Court subsequently withdrew its order granting the pharmacies' motion to compel, but explained, "it is likely the Track Three Pharmacy Defendants will again move for production of the same OARRS data from OBOP, and that this Court will order it be produced." Dkt. 3313 at 2.

On April 30, 2020, the Court established the Lake and Trumbull County, Ohio cases as MDL Track 3, and allowed those plaintiffs to amend their complaints to include dispensing claims alleging that the Pharmacy Defendants filled improper prescriptions, and that doing so was a public nuisance that caused the opioids crisis in Lake and Trumbull Counties. Dkt. 3282. Yet, according to the ARCOS data, the Pharmacy Defendants make up just 58 percent of the dispensing market in those two counties between 2006 and 2014. The Pharmacy Defendants have no information about most of the prescribers, prescriptions, or dispensing practices

associated with the dispensers that make up the other 42 percent. Those non-defendant dispensers received more than 71 million dosage units of opioids between 2006 and 2014, according to ARCOS data.

On June 10, the Pharmacy Defendants served a new subpoena on the Board seeking, among other things, the limited additional OARRS data at issue here, i.e., data identifying the dispensers and prescribers associated with the millions of opioids prescriptions in Lake and Trumbull Counties that the Pharmacy Defendants did not fill.[3] The Board objected, raising privacy concerns.

By contrast to the Board's position here, on December 13, 2019, in related state-court opioids litigation, the State of New York voluntarily produced data from its own prescription monitoring program, I-STOP, including prescriber and dispenser data similar to what the Pharmacy Defendants seek here. The produced I-STOP data covers the entire timeframe that New York's prescription monitoring program has been in effect.

The Pharmacy Defendants met and conferred with the Board multiple times, but the Board refused to produce any additional OARRS data. The Pharmacy Defendants therefore bring this motion to compel, seeking production of prescriber and dispenser information from the OARRS database, as well as a general update of the Board's previous production from OARRS, to cover the entire timeframe of 2006 to the present. The Pharmacy Defendants agree that the Board may designate the production under the Court's existing HIPAA Protective Order.

The Court should grant the motion, and order the Board to produce the data in time for the Pharmacy Defendants' experts to opine upon it in advance of the Track 3 trial.

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[3] The Pharmacy Defendants' Track 3 subpoena is narrower than the Track 1B subpoena. It is limited to the list of prescription opioids and other medications that the Court has ordered the Pharmacy Defendants to produce.

STANDARD

"Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." FED. R. CIV. P. 26(b)(1). The rules allow for inquiry into the affairs of both litigants and third parties. *See Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 30 n.15 (1984). Thus, "[a] command in a subpoena to produce documents, electronically stored information, or tangible things requires the responding person to permit inspection, copying, testing, or sampling of the materials." FED. R. CIV. P. 45(a)(l)(D).

Under Rule 45, the party refusing to comply bears the burden of showing good cause. 9A C. WRIGHT & A. MILLER, FEDERAL PRACTICE & PROCEDURE § 2463.2 (3d ed. 2017). "At any time, on notice to the commanded person, the serving party may move the court ... for an order compelling production or inspection," FED. R. CIV. P. 45(d)(1)(B)(i), and the court "may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena," FED. R. CIV. P. 45(g).

ARGUMENT

I. The Court Has Already Found That the Pharmacy Defendants Have a Substantial Need for the Limited Additional Data Requested from the OARRS Database.

The Pharmacy Defendants cannot fairly defend themselves against plaintiffs' public nuisance claims without the limited additional information sought from OARRS. OARRS is the only source for identifying the prescribers and dispensers associated with each opioid prescription filled in Ohio. That information is necessary to show widespread alternative causes

of the alleged nuisance, e.g., the large number of "over-prescribers," "pill mills," and other dispensers plaintiffs chose not to sue.[4]

This Court has already held that "the Pharmacy Defendants' need for the data in this litigation outweighs any countervailing concerns." Dkt. 3168 at 7. The Court has recognized the need for this data to show alternative causation repeatedly. At a court conference in December, the Court stated, "you can get that data and you can run things and you can put in that, hey, those are the people who caused the public nuisance, not us….You're free to do that….[The Pharmacy Defendants] can defend the case that way." 12/4/19 Hr'g Tr. 49:1-10; *see also* Dkt. 3055 at 3 ("discovery of the OARRS database may be helpful and necessary"). The Pharmacy Defendants cannot do that, however, unless the Court once again orders the Board to produce the data.

The OARRS data is also necessary to identify "doctor shoppers" in a de-identified fashion. The Board has already anonymized patient-identifying information. The produced OARRS data identifies each patient by a unique number that travels with that patient from prescription to prescription, doctor to doctor, pharmacy to pharmacy. By contrast, the Pharmacy Defendants' own data contains only their own dispensing information. The parties will not be able to use the Pharmacy Defendants' own data to identify patients who filled prescriptions at multiple pharmacies—or prescribers who wrote multiple prescriptions for such patients.

[4] For example, the OARRS data is necessary to identify the dispensing practices of "pill mills" such as those that recently closed in Scioto County, and the prescribing practices of the criminal doctors associated with those pill mills, both of which clearly contributed to the opioids crisis. *See* John Caniglia, *The end of an era: Pill mills are gone at Ohio's epicenter, but crisis continues*, Cleveland Plain Dealer (Dec. 1, 2019) *and* John Caniglia, *Key players convicted in Scioto County's pill mills*, Cleveland Plain Dealer (Dec. 1, 2019), *both available at* https://www.cleveland.com/news/2019/12/the-end-of-an-era-pill-mills-are-gone-at-ohios-opioid-epicenter-but-crisis-continues.html.

OARRS is the only dataset anywhere that allows the tracing of individuals across prescribers and pharmacies. Therefore, it is the only dataset that allows the identification of doctor shoppers who sought pills from multiple places, as well as the over-prescribers who wrote those patients' prescriptions. Identifying those patients and prescribers is a primary purpose of OARRS. *See* https://www.ohiopmp.gov/About.aspx. The Board has argued that the Pharmacy Defendants should be required to issue scores of third-party subpoenas to obtain this data from the non-defendant pharmacies that filled those prescriptions. But as this Court has already recognized, collecting the data from third parties—even if possible—would not allow the cross-referencing of prescriptions or patients, as each pharmacy uses its own unique identifiers to de-identify patient information. *See* Dkt. 3168 at 4–5.[5]

Because the Court has ordered the Pharmacy Defendants to produce statewide dispensing data, Dkt. 3341 at 3 n.4, the Pharmacy Defendants need the Board to produce statewide OARRS data as well. Likewise, the Pharmacy Defendants need OARRS data from 2006 to the present, because that is the temporal scope of the data that the Court has ordered the Pharmacy Defendants to produce. *Id.*

II. The Court Has Already Found That the Board Cannot Show Good Cause for Noncompliance with the Subpoena.

This Court previously ruled that there is no countervailing interest that would justify the Board's withholding of this limited additional data. *See* Dkt. 3168 at 7. First, it is indisputably,

[5] Attempts to collect this data from third parties also would grind fact discovery to a halt while subpoenas are issued, negotiated, and litigated. The Pharmacy Defendants served subpoenas on some of these third parties in Track 1B and hit a brick wall. None of them produced a single line of data. The Board, on the other hand, has already produced much of the data the pharmacies seek. It should not take long or impose any significant burden for the Board to produce the rest.

critically relevant, and potentially even case dispositive. The data may well show that any public nuisance relates to non-party dispensing or prescribing conduct, not the Pharmacy Defendants.

Second, there is little burden to the Board in producing it. The Board already has pulled the data in question, taken the extra step of anonymizing it, and produced it in this litigation. In fact, the Board conceded in its previous opposition to McKesson's motion to compel that the Board pulls OARRS data routinely, every few months, for research purposes. All the Pharmacy Defendants ask is that the same data previously produced be updated and reproduced with the ***dispenser*** and ***prescriber*** fields included.

Third, the privacy concerns raised by the Board, though certainly real and substantial, cannot bar production here. The Court previously found that the Pharmacy Defendants "clearly take seriously the privacy of their patients," dismissing the Board's privacy concerns. Dkt. 3168 at 6.[6] And the Court has already ordered the Pharmacy Defendants to produce their own dispensing data, over objection, holding that any privacy concerns are adequately addressed by the Court's protective orders. The Pharmacy Defendants are entitled to OARRS data, subject to the same protective orders, to defend against plaintiffs' claims.

Finally, the Board's objections that certain federal and state confidentiality statutes preclude production of the data are misplaced. As this Court previously concluded, "these statutes are premised entirely on the concern that disclosure of data would allow identification of patients." Dkt. 3168 at 7. But the Pharmacy Defendants do not seek patient-identifying information such as patient name, address, or date of birth.

[6] The Court also concluded that the Board's "argument that Pharmacy Defendants should be required to gather and collate the equivalent of OARRS data themselves [from other third parties], rather than obtain it in one complete package from OBOP, reveals OBOP is concerned more with data-proprietorship than the privacy of the information the data contains." Dkt. 3168 at 6.

Moreover, these statutes inform, but do not limit, the Court's discretion regarding the scope of discovery under Rule 45. *See, e.g.*, *Everitt v. Brezzel*, 750 F. Supp. 1063, 1065–1066 (D. Colo. 1990) (holding that the Federal Rules of Civil Procedure, rather than Colorado case law, governed discovery of police files in civil rights action: "Discovery in the federal courts is governed by federal law as set forth in the Federal Rules of Civil Procedure, whether federal jurisdiction is based on the existence of a federal question or on diversity of citizenship."); *Sharon Steel Corp. v. Travelers Indem. Co.*, 26 F.R.D. 113, 116 (N.D. Ohio 1960) (granting motion to compel production of general counsel's notes prepared in anticipation of trial based on good cause shown under FED. R. CIV. P. 34 despite contrary state ruling and explaining, "we cannot afford to allow state court rulings to influence what we consider to be the proper interpretation of the federal rules concerning discovery"); *see also* 8 C. WRIGHT & A. MILLER, FEDERAL PRACTICE & PROCEDURE § 2005 (3d ed. 2019) ("State law is of very little relevance to discovery in a federal action.").

The fact that the Board has already voluntarily produced much of the information in the OARRS database, coupled with the State of New York's production of its own prescription monitoring data in related state court proceedings—including the same type of data sought here—also significantly undercuts the Board's arguments against production. The Board's concerns do not trump the Pharmacy Defendants' genuine need for this data under Rule 45.

CONCLUSION

Because the benefit substantially outweighs any burden from producing the limited data sought, the Pharmacy Defendants ask this Court to order the Board to reproduce the statewide OARRS data, from 2006 to present, identifying the prescribers and pharmacies associated with the dispensing data the Board has already produced.

Dated: July 1, 2020

Respectfully submitted,

/s/ *Kaspar J. Stoffelmayr*

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record on July 1, 2020.

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	**MDL No. 2804**
	Case No. 17-md-2804
THIS DOCUMENT RELATES TO:	**Hon. Dan Aaron Polster**
County of Lake, Ohio v. Purdue Pharma L.P., et al. Case No. 18-op-45032 (N.D. Ohio)	
The County of Trumbull, Ohio v. Purdue Pharma L.P., et al. Case No. 18-op-45079 (N.D. Ohio)	
"Track Three Cases"	

NON-PARTY STATE OF OHIO BOARD OF PHARMACY'S MEMORANDUM IN OPPOSITION TO MOTION TO COMPEL

I. INTRODUCTION

The Pharmacy Defendants[1] have asked this Court to compel the State of Ohio Board of Pharmacy ("the Board") to produce data from the Ohio Automated Rx Reporting System ("OARRS"). When a patient goes into a pharmacy to fill a prescription for a controlled substance, the pharmacy is required to submit information about that dispensation into the OARRS database – including details about the patient. For over the last decade, pharmacists around the state have been

[1] The Pharmacy Defendants are CVS Rx Services, Inc. CVS Indiana, LLC, CVS Pharmacy Inc. and Ohio CVS Stores, LLC, Rite Aid of Maryland, Inc. Rite Aid Hdqtrs. Corp., Walgreen Co., Walgreen Eastern Co., HBC Service Company, Giant Eagle, Inc., Discount Drug Mart, and Walmart Inc.

Exhibit C

diligently entering information about their dispensation of controlled substances into OARRS. More than half of all Ohioans are listed as patients in the OARRS database.

This Court should deny the motion to compel for two reasons: (1) the information is privileged under Ohio law and (2) the Pharmacy Defendants already have the information that they need to defend against the counties' claims.

Because of the extreme sensitivity of its contents, the OARRS data is confidential under state law – specifically O.R.C. 4729.80 and 4729.86. The Board is only authorized to release OARRS information for certain reasons. The statute prohibits the Board from releasing OARRS data that will "identify a person, including any licensee or registrant of the board or other entity[.]" O.R.C. 4729.80(C). Moreover, the statue statute expressly prohibits the use of OARRS information in civil cases. Under Fed. R. Evid. 501 and *Jewell v. Holzer Hosp. Found., Inc*., 899 F.2d 1507, 1513 (6th Cir. 1990), this Court is obligated to apply Ohio confidentiality law because this case is proceeding only under a state law nuisance claim.

In addition, the research extract already provides all of the information the Pharmacy Defendants will need. They want to identify "doctor shoppers" in a deidentified fashion, they already have all the tools to do so. They want to identify pharmacists and prescribers who were far outside the bounds of acceptable behavior. The research extract already allows them to do so.

Simply put, the Board not only had good cause to challenge the subpoena, the Board has binding precedent that mandates that this Court deny the motion to compel.

II. STATEMENT OF FACTS

The OARRS Program. OARRS records are highly confidential, and the Board tightly controls access. *See* Acceptable Use Policies at https://www.ohiopmp.gov/Documents.aspx. The confidentiality and security of data is central to the operation of all prescription drug monitoring

programs ("PDMP"). *See Whalen v. Roe*, 429 U.S. 589, 600-602 (1977) (affirming New York's PDMP in part because of its confidentiality).

OARRS includes a patient database which contains records of all controlled substances and drugs of concern dispensed to outpatients. The patient database has a portal limited only to an authorized user, which is intended to be used by both law enforcement and other statutorily-designated categories of users to ensure compliance with Ohio law. *See* https://www.ohiopmp.gov/. In a typical patient database transaction, a patient presents a prescription for a controlled substance to a licensed pharmacist in the state of Ohio. After dispensing that medication, the pharmacist logs the following information into OARRS pursuant to Ohio Adm. Code 4729:8-3-02:

1. Pharmacy Drug Enforcement Administration registration number
2. Pharmacy name
3. Pharmacy address
4. Pharmacy telephone Number
5. Patient full name
6. Patient residential address
7. Patient telephone number
8. Patient date of birth
9. Patient gender
10. Prescriber's full name (first name and last name)
11. Prescriber's Drug Enforcement Administration registration number
12. Date prescription was issued by the prescriber
13. Date the prescription was dispensed or sold by the pharmacy
14. Indication of whether the prescription dispensed is new or a refill
15. Number of the refill being dispensed
16. National drug code of the drug dispensed
17. Number of refills authorized by the prescriber
18. Quantity of the drug dispensed
19. Number of days' supply of the drug dispensed
20. Serial or prescription number assigned to the prescription order
21. Source of payment for the prescription

22. Pharmacy national provider identification (NPI) number

23. Prescriber's national provider identification (NPI) number

24. ICD-10-CM or CDT diagnosis/procedure code

Access to the patient database is tightly controlled; no one outside of the limited OARRS staff at the Board has unfettered access – not even Board investigators. Limited access to the patient database is granted to pre-approved individuals for specific authorized purposes. *See* O.R.C. 4729.80(A). Access is granted to specific individuals, not offices or roles. For example, an individual police officer or government agent may be granted an OARRS account in his or her own name for use in connection with his or her own investigation of drug abuse. Agencies or departments do not have a "universal" account. Nor may anyone access the database for anything other than in connection with a specific case. And the scope of information OARRS makes available to any account holder is limited to only that information which would be appropriate for them to access. In the case of law enforcement officials, for instance, authorization to access an individual's OARRS data is only granted after entry of a case number and approval for access by their supervisor. *See* Ohio Admin. Code 4729-37-08(B); *State v. Meyers*, 12th Dist. App. No. CA2014-02-002, 2015-Ohio-160, 27 N.E.3d 895, ¶ 13. Even then, the official would only have access to the records necessary to complete that particular investigation.

The same access restrictions are true of any other type of user. Each user's access is limited to only the type of information necessary to perform their official duties. Among those granted access to OARRS are health care professionals who prescribe reportable medications and pharmacists who dispense those medications. Those authorized to access the OARRS database may only do so to the extent necessary. For instance, physicians may only access those records directly related to patients presently under their care or to their own prescribing. O.R.C.

4729.80(A)(5). When the Board discovers abuse or misuse of the database, it both refers violators for criminal prosecution and revokes or restricts access for egregious abuses of the database. Improper access to, or use or distribution of, information contained within the OARRS database can be punishable by a felony. *See* O.R.C. 4729.99(J); *Meyers*, 27 N.E.3d at 899.

The Board Provided A "Research Extraction." As part of an amicable agreement with McKesson, a defendant that has since settled its case, the Board provided a "research extraction" of the entire OARRS database, which contained dispensations of controlled substances made by Ohio pharmacies dating back to 2008. Notably, the Pharmacy Defendants also received this research extraction.

The research extraction only included some of the database fields. And for some of the fields, a randomized "hash" was given to each individual patient, along with separate "hash" fields for prescriber names and pharmacy names.

III. This Information Is Confidential Under State Law

A. This Court Must Apply State Law In Diversity Jurisdiction Cases.

Under Fed. R. Evid. 501, "in a civil case, state law governs privilege regarding a claim or defense for which state law supplies the rule of decision." In reviewing a claim of psychotherapist-client privilege, the Supreme Court noted that "if only a state-law claim had been asserted in federal court, the second sentence in Rule 501 would have extended the privilege to that proceeding." *Jaffee v. Redmond*, 518 U.S. 1, 15, n.15 (1996).

In diversity jurisdiction cases it is black-letter law in this Circuit that Fed. R. Evid. 501 provides that the existence of confidentiality is "determined in accordance with state, not federal law." *Jewell v. Holzer Hosp. Found., Inc*., 899 F.2d 1507, 1513 (6th Cir. 1990). Applying O.R.C. 2317.12 and Ohio case law, the *Jewell* court concluded that (1) physician-patient privileged

applied, (2) had not been waived, and (3) a party could not raise the issue of invocation of patient-client privilege before the jury. *Id.* at 1513-1514.

"District courts within the Sixth Circuit have applied Rule 501's principle—that is, that state law governs privilege where state law supplies the rule of decision—in a broad spectrum of cases." *SBAV LP v. Porter Bancorp, Inc*., 2015 U.S. Dist. LEXIS 41162, at *16 (W.D. Ky. 2015). Numerous district courts in this Circuit have applied Jewell in diversity cases and evaluated state law confidentiality provisions established in state statutes. See e.g.s *State Farm Mut. Auto. Ins. Co. v. Elite Health Ctrs., Inc*., 399 F. Supp. 3d 708, 711 (E.D.Mich.2019) (applying marital privilege found in MCL 600.2162(4)); *Babcock & Wilcox Power Generation Group, Inc. v. Cormetech, Inc*., 81 F. Supp. 3d 632, 640 (N.D.Ohio 2015) (applying mediation communication privilege found in O.R.C. 2710.03); *SBAV LP*, 2015 U.S. Dist. LEXIS 41162, at *16 (W.D. Ky. 2015) (finding that K.R.S. §286.3-470 does not prohibit disclosure of bank examination documents); *Freudeman v. Landing of Canton*, 2010 U.S. Dist. LEXIS 55273, at *7 (N.D. Ohio, 2010) (applying peer-review and physician patient privileges under O.R.C. 2317.02, 2305.252 and 2305.253).

Ohio law "supplies the rule of decision" because the Track Three cases against the Pharmacy Defendants are based on O.R.C. 4729.35 and Ohio common law. In their second amended complaints, Trumbull and Lake Counties allege that the Pharmacy Defendants have created a "common law absolute public nuisance" under O.R.C. 4729.35 by "marketing, distributing, dispensing, and selling opioids in ways that unreasonably interfere with the public health, welfare, and safety in Plaintiff's community." *Lake County Second Amended Complaint*, Doc. #19, p. 197, 198 (PageID #1011, 1012); *Trumbull County Second Amended Complaint*, Doc. #13, p. 197, 198 (PageID #639, 640).

There are no federal causes of action pending in the Track Three cases. Both Trumbull and Lake Counties stated in their Second Amended Complaints that, consistent with this Court's order, "only claims against pharmacy defendants for public nuisance will proceed in Track Three[.]" *Lake County Second Amended Complaint,* Doc. #19, p. 1, n.1 (PageID# 822); *Trumbull County Second Amended Complaint,* Doc. #19, p.1, n.1 (PageID# 443).[2]

Pharmacy Defendants rely on three citations to support its claim that state law is irrelevant. None of them are binding precedent or even purport to overrule the Sixth Circuit's binding precedent found in *Jewell.* For example, Pharmacy Defendants cite to dicta in *Everitt v. Brezzel,* 750 F.Supp 1063, 1065-1066 (D.Colo. 1990). That court expressly noted that there was a critical difference between a case premised on federal law and state law. "In order to determine whether plaintiffs are asking for 'privileged' information, I must first consider whether to look at federal law or state law." *Id.* at 1066. The court concluded – unremarkably – that since that lawsuit was premised under 42 U.S.C. §1983 that "the federal common law of privileges will govern." *Id.*

Nor does *Sharon Steel Corp. v. Travelers Indem. Co.,* 26 F.R.D. 113, 116 (N.D. Ohio 1960) compel a different result. That court was faced with the situation where a state court judge in a "companion" case pending in state court found that some materials were not discoverable as work product. The court concluded that it would apply the federal rules, not Ohio rules of procedure. But that is beside the point – the Board agrees that the *federal* rules of evidence apply here: specifically Fed. R. Evid. 501. The *Jewett* court has conclusively held that in resolving privilege

[2] Neither Trumbull nor Lake Counties have expressly invoked federal common law as a basis for their claims. Notably, this Court rejected such an effort in *Blackfeet Tribe of the Blackfeet Indian Reservation v. AmerisourceBergen Drug Corp.* (In re Natl. Prescription Opiate Litigation), 2019 U.S. Dist. LEXIS 101659, at *95 (N.D. Ohio, Apr. 1, 2019).

issues in discovery, federal courts are required to apply state law privileges when the case is premised on a state law cause of action.

Finally, the Pharmacy Defendants cite to Wright & Miller for the statement that "State law is of very little relevance to discovery in a federal action." Motion at 11 (quoting 8 Wright & Miller [sic], § 2005 (3rd Ed. 2019)). Immediately thereafter Wright & Miller identified two key exceptions, one of which is that "Fed. R. Evid. 501 decrees that, as to issues on which state law provides the rule of decision, state law should determine whether there is a privilege." 8 Wright, Miller & Marcus, § 2005, p. 51, n.6 (3rd Ed. 2018). This case meets one of those exceptions because the Track Three cases brought by Trumbull and Lake counties only involve state-law nuisance claims.

B. The Identities of Licensees In The OARRS Database Is Confidential.

Under O.R.C. 4729.80, the Board is permitted to release information from OARRS only under several specific circumstances. While there is a provision that authorizes the Board to comply with a court order "in connection with the investigation or prosecution of a possible or alleged criminal offense" (O.R.C. 4729.80(A)(4)) and a provision for responding to grand jury subpoenas (O.R.C. 4729.80(A)(3)), there is no such provision for such disclosure in a civil case.

Ohio law regarding the admissibility of OARRS information in civil cases cannot be clearer: "A person shall not use information obtained pursuant to division (A) of section 4729.80 of the Revised Code as evidence in any civil or administrative proceeding." O.R.C. 4729.86(B).

Under O.R.C. 4729.86(A)(1), it is unlawful to improperly disseminate information from the OARRS database except for the limited exceptions listed in O.R.C. 4729.80(A) and (B). Improper disclosure of OARRS data is a criminal offense under O.R.C. 4729.99. There is no grant of immunity nor protection that can be afforded to the Board's Executive Director or Director of

the OARRS database for disclosing OARRS content other than for express purposes set forth in the governing confidentiality statutes.

`The Pharmacy Defendants are asking this Court to order the Board to disclose the names of pharmacies and prescribers. Such an order would flatly contradict an Ohio statute expressly prohibiting the Board from releasing information which will "identify a person, **including any licensee or registrant of the board or other entity**[.]" O.R.C. 4729.80(C) (emphasis added).

The Board licenses Ohio pharmacies. See O.R.C. 4729.01(Q) (definition of terminal distributor of dangerous drugs includes pharmacies) and 4729.54 (terminal distributors must obtain a license). Individuals who prescribe controlled medications are licensed by various entities, including the State of Ohio Medical Board (O.R.C. 4731.09 and 4730.10), the Ohio Board of Nursing (O.R.C. 4723.41), the Ohio State Dental Board (O.R.C. 4715.10), and the Veterinary Medical Licensing Board (O.R.C. 4741.11).

Simply put, the Pharmacy Defendants cannot require the Board to violate Ohio law and disclose OARRS data that will identify state of Ohio licensees. The purposes for which the Board may release information from the database are limited and express. See O.R.C. 4729.80(A). This does not fall under any of the acceptable reasons for disclosure.

C. Pharmacy Defendants Are Indirectly Seeking Patient Identities.

Revealing the unique identifying numbers for each and every pharmacy and prescriber to Pharmacy Defendants would be tantamount to providing the Defendants with the unique identifying numbers of individual patients for well over half of all Ohioans. O.R.C. 4729.80(C) prohibits the release of data from OARRS that can be used to "identify a person" including patients.

It is difficult to understate the breadth of information that is contained in the OARRS database. This is not the medical file for a single patient or even the patient files for every patient who saw a single doctor. Or even every patient who went to a specific hospital. These are the private medical records of over seven million Ohioans – sweeping up the personal matters of both public figures and private individuals, from children to adults in the state. The information would permit the Defendants to unlock millions of people's prescribing history.

The Pharmacy Defendants are not limiting their requests to a specific time frame, or those that prescribed or dispensed to patients from Trumbull and Lake Counties. The research database in the possession of the Pharmacy Defendants is not limited to prescription opioids. Medicines like testosterone cream, Ambien, Xanax and Ritalin are also controlled substances under Ohio and federal law and are wholly included in the data.[3] These drugs are not part of these lawsuits, but the Pharmacy Defendants will receive the keys to unlocking that information as well.

Make no mistake, the Pharmacy Defendants expressly state that they are seeking this information in order to identify "doctor shoppers." Motion at 9. That is, the Pharmacy Defendants are seeking to identify specific patients. (As will be discussed below, the Pharmacy Defendants already have the tools at their disposal to make that determination using existing deidentified data.)

The Pharmacy Defendants here are the biggest pharmacy chains in Northeast Ohio. They have extensive privately-held databases detailing what medications they each have dispensed to

[3] The Pharmacy Defendants subpoena in this case also demands all OARRS data about a number of medications. That part of the request is *not* part of this motion to compel. The motion to compel before this Court involves the names and addresses of *all* pharmacies and prescribers in the OARRS database – not just ones that prescribed or dispensed the more limited list of medications found in the subpoena. . Regardless, the Board objects to any order that would require disclosure of all pharmacies and prescribers or those limited to the drug dispensations specified in the subpoena.

patients. Providing the Pharmacy Defendants with the identity of all prescribers and pharmacies for each prescription listed in the Research Extraction (which the Defendants already have received) will essentially provide them the identities of countless patients in the OARRS database with only a modicum of reverse engineering.

For example, if Walgreens (one of the Pharmacy Defendants) was supplied with all information for a particular prescription that was filled at a Walgreens pharmacy – the drug prescribed, the date the prescription was written, the date the prescription was filled, quantity, number of refills, prescriber name, and specific pharmacy name and address at which the prescription was filled – Walgreens could locate that particular prescription within its records. Walgreens' records would necessarily include the patient name for the prescription, thus, revealing the identity of that patient. Walgreens would then know the unique identifying number, or hash, used for that patient in the Research Extraction.

Walgreens would have then the ability to search the database for every purchase that patient has ever made at any pharmacy (not just Walgreens) even years before or years after that patient was a Walgreens customer.

But if the data being provided can be used to "identify a person" then it is barred from disclosure by O.R.C. 4729.80(C), even if the Pharmacy Defendants promise that they won't peek behind the curtain.

IV. The Pharmacy Defendants Already Have The Information To Identify "Doctor Shoppers" and "Pill Mills" in De-Identified Fashion.

The Pharmacy Defendants insist that they are seeking this information solely to identify pill mills by name and "'doctor shoppers' in a de-identified fashion." Motion at 8. They already have the tools at their disposal necessary to make these determinations.

As noted above, the Board has already provided a research extraction. Here is a single entry of the research extraction already in the Pharmacy Defendants' possession:[4]

DateFilled	01/01/2015
RxNumber	123456
RefillCode	0
Quantity	30
DaysSupp	30
NDC	54092038101
Drug	ADDERALL XR 5 MG CER
TherClassCode	2820040010
TherClassDesc	Amphetamine & Comb.
DateWritten	01/01/2015
NumOfRefillsAuth	0
PaymentType	4
PharmacyHash	1111AAAAA11AA1111A11AA1AA11AA1111AAAAA
PharmacyZip	445
PharmacyBACCode	A
PharmacyBACSubCode	3
PrescriberHash[5]	1AA11AA111A1111AA111111AA11A111111AA111A1
PrescriberZip	445
PrescriberBACCode	C
PrescriberBACSubCode	
PrescriberSpecialty	Pediatric medicine
PatientGroupIDHash	A1A1111A11111A11AAAAAAA1AA11111A11111A11A1
PatientAge	8
PatientSex	2
PatientZip	445

[4] This is based on an actual prescription. Out of an abundance of caution, counsel has randomized the date the prescription was written and filled, the RX number, the zip code, and for the unique identifiers, changed any numbers to a 1 and any letters to an A. The research extraction provides the first three numbers of a zip code.

[5] In the chart listed on page 4 of the motion, the Pharmacy Defendants state that the Board did not provide patient names, pharmacy names or physician names with an asterisk saying "Unique Patient ID number supplied instead." Motion at 4. This is misleading. The research extraction included unique numbers for pharmacies and prescribers as well.

Using the unique "hash" for each patient, the Pharmacy Defendants can sort the entire database by patient. This "hash" will be identical for a specific patient for all transactions in the database. Thus, the Pharmacy Defendants can identify every prescription filled for a specific patient that is stored in OARRS – but the Pharmacy Defendants would not know the name of the patient.

For instance, if the Pharmacy Defendants wanted to identify patients that received prescriptions for Oxycontin 40 mg (an opioid that was particularly abused) from more than five prescribers, they could simply filter the database for entries in the "Drug" field that state Oxycontin 40, then sort the database so that only those patients with at least five different individuals in the "PresciberHash" are listed, allowing Pharmacy Defendants to identify a list of de-identified patients that likely were doctor shoppers.

The Pharmacy Defendants could do the same for the pharmacies and prescribers – again, without knowing their name, as there is a hash assigned to each pharmacy and prescriber in the same manner as that assigned to a patient. So, if the Pharmacy Defendants want to know which pharmacies have the highest number of Oxycontin 40 dispensations, then they can simply sort from the database already in their possession. They could do the same for prescribers. The Pharmacy Defendants will have to rely on the individual "PharmacyHash" and "PrescriberHash" used in the research extractions.

In addition to being able to identify prescribers and pharmacies with a unique hash, the Board annually produces data detailing doctor shopper statistics in its reports. Those documents were requested and produced months ago in response to an earlier subpoena. Those documents are readily available on the Board's website and are a viable alternative should Defendants be

seeking to use information pertaining to doctor shoppers in its case, see for example https://www.ohiopmp.gov/documents/Annual%20Report%20(2018).pdf.

V. This Information Is Confidential Under Federal Law.

A. 42 U.S.C. § 290dd-2 Bars Disclosure of Some OARRS records

Supplying Pharmacy Defendants with the tools to discover individual patient information would violate federal law. An unidentifiable number of records are explicitly precluded from disclosure by federal law. Among the records contained within OARRS are records of prescriptions for drugs used in the treatment of substance abuse. For instance, two common drugs used in the treatment of substance abuse are the opioids methadone and suboxone. Both are opioids and controlled substances monitored by the OARRS database.[6] Additionally, medical practitioners frequently prescribe other medications, such as benzodiazepines, to assist in substance abuse treatment. *See* S. Nielsen et al, *Concurrent buprenorphine and benzodiazepines use and self-reported opioid toxicity in opioid substitution treatment*, ADDICTION, 102(4):616-22 (2007)(two thirds of those using suboxone for substance abuse treatment report concurrent benzodiazepine use). Records of substance abuse treatment are confidential and not subject to disclosure except in very limited circumstances, not applicable here, by operation of 42 U.S.C. § 290dd-2. Violation of this provision is punishable by federal criminal penalties. *See* 42 U.S.C. §290dd-2(f). Defendants' ability to identify specific patients by utilizing the requested information would lead to Defendants gaining information regarding those patients' prescriptions for drugs used in the treatment of substance abuse. This is precisely what is prohibited by § 290dd-2.

B. NASPER Prohibits Disclosure of the Information Contained in the OARRS Database

[6] Suboxone (buprenorphine) is a Schedule III controlled substance; Methadone is a Schedule II controlled substance. *See* 21 C.F.R. §§ 1308.12; 1308.13.

Defendants are not entitled to even those records in the database not prohibited from disclosure by § 290dd-2. The millions of people with prescription drug records in OARRS have a right to privacy in that information. *See Whalen v. Roe*, 429 U.S. 589 (1977); *Douglas v. Dobbs*, 419 F.3d 1097, 1102 (10th Cir. 2005). *See also Northwestern Mem. Hosp. v. Ashcroft*, 362 F.3d 923, 928-29 (7th Cir. 2004). The Board has access to this information only because it is fulfilling the important governmental purpose of monitoring the flow of dangerous drugs within Ohio's borders. To provide access to identified patient information, whether directly or indirectly as Defendants are currently requesting, in connection with a civil suit for monetary damages would be a gross violation of the privacy rights of millions of people and would interfere with the Board's and other law enforcement agencies' efforts to combat the opioid crisis. This Court should deny Defendants' motion to compel because the OARRS database is confidential by law. But even if the federal and Ohio statutes protecting the confidentiality of the OARRS database are insufficient to warrant protection here, this Court should find that the information contained within the database is privileged within the meaning of Rule 501.

In order to receive federal funding under the National All Schedules Prescription Electronic Reporting ("NASPER") Act, Ohio had to enact its confidentiality laws. Accordingly, Ohio's confidentiality laws for OARRS are, in essence, federal confidentiality laws. *See South Dakota v. Dole*, 483 U.S. 203, 206 (1987) (Congress may "further broad policy objectives" by conditioning federal funding.) From the very beginning, the need to protect the security of the information to be contained in a state PDMP database was well-understood. When the federal government decided that it was in the national interest to encourage the development of state PDMPs, security of the information was paramount. NASPER specified not only what information should be

contained within a state PDMP database, but also that use and disclosure of that information should be limited to approved individuals for proper purposes. *See* Pub. L. No. 109-60 Sec. 399O(f), (g). Specifically, NASPER required that states seeking funding develop a statutory scheme authorizing release of PDMP database information to: 1) healthcare practitioners "for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient;" 2) law enforcement personnel only when "related to an individual investigation or proceeding involving the unlawful diversion or misuse of a schedule II, III, or IV substance, and such information will further the purpose of the investigation or assist in the proceeding;" 3) another state PDMP; 4) agents of certain specified federal agencies who certify "that the requested information is necessary for research to be conducted by such department, program, or administration, respectively, and the intended purpose of the research is related to a function committed to such department, program, or administration by law that is not investigative in nature;" 5) state agents charged with the implementation of the PDMP database. *See* Pub. L. No. 109-60 Sec. 399(O)(f). NASPER also required that States seeking funding from HHS enact legislation imposing penalties for the unauthorized use and disclosure of information retained within a PDMP. *See* Pub. L. 109-60 Sec. 399(O)(a)(2); (c)(2).

Consistent with the requirements set by NASPER, the Ohio General Assembly enacted O.R.C. 4729.80 to restrict access to the database. The individuals who can access OARRS tracks the language of NASPER, with only the following being eligible to access the database: 1) healthcare practitioners;[7] 2) law enforcement and Court personnel;[8] 3) another state PDMP;[9] 4)

[7] O.R.C. 4729.80(A)(5), (6), (12), (21); (B)(1), (2).
[8] O.R.C. 4729.80(A)(1), (2), (3), (4), (16), (17)
[9] O.R.C. 4729.80(A)(14).

other state agencies required to use prescription data to carry out their designated functions;[10] 5) an individual seeking their own records;[11] 6) peer review committees[12], and 7) the Director of Health for the purpose of implementing the Ohio violent death reporting system.[13] And, as previously noted, improper access to, or distribution of, OARRS data may be a felony. As the state law confidentiality provisions applicable to OARRS are mere reflections of the federal prerogative to preserve the confidentiality of sensitive patient information, this Court should find that any de-identified OARRS information is privileged and not subject to disclosure.

VI. What Occurred In New York Is Irrelevant.

The Pharmacy Defendants raise the curious argument that OARRS data is not protected because the State of New York apparently chose to turn some or all of this data over during state court proceedings. Notably, they have not attached any documents to actually support this claim, so the Board is not in any position to actually comment on what was turned over, why New York did so, or what protections were in place.

What happened in New York is irrelevant. O.R.C. 4729.80 and 4729.86 obviously would not apply to New York's PDMP. And even if New York voluntarily waived protections for patient data, that does not mean that the Board is required to follow suit – especially where binding Sixth Circuit precedent establishes that the plain language of Ohio's confidentiality statutes will bar disclosure.

VII. The Existing Protective Orders Are Insufficient

[10] O.R.C. 4729.80(A)(8), (9), (10), (11).
[11] O.R.C. 4729.80(A)(7), (19).
[12] O.R.C. 4729.80(A)(21).
[13] O.R.C. 4729.80(A)(13).

In the event this Court grants the motion to compel (which it should not), it should require a far more stringent protective order than is currently in place. The dataset in the Pharmacy Defendants already contains the dispensing data for more than half of the people in Ohio. As noted above, disclosing the identities of pharmacies and prescribers is tantamount to giving the Pharmacy Defendants the identities of millions of patients.

If this Court orders that the Board produce the requested information, in addition to the other existing orders, it should order that only a single attorney and a single consultant for each Pharmacy Defendant be permitted to have access to the OARRS data. The Board is not meaning to cast aspersions on any of the counsel. But the sensitivity of this data is extraordinarily high and there are obviously dozens (if not hundreds) of law firm personnel and consultants working on the Ohio litigation. Unlike the OARRS database itself, there is no mechanism to track impermissible access so limiting the individuals that may view it is a reasonable protection to mitigate the risk.

VIII. Conclusion

In the end, this is pretty simple. In the Sixth Circuit, federal courts apply "state law privileges when reviewing a claim or defense for which state law supplies the rule of decision." This case involves claims of public nuisance under Ohio law. Ohio privileges apply.

Ohio law forbids the Board from releasing information in the OARRS database about "any person" – including licensees – unless an exception applies. And while OARRS data can be provided in a criminal case, there is no comparable provision for civil cases. On the contrary, "A person shall not use information obtained pursuant to division (A) of section 4729.80 of the Revised Code as evidence in any civil or administrative proceeding." O.R.C. 4729.86(B).

This Court should deny the motion to compel.

Respectfully submitted,

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Counsel for Interested Party Ohio State Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that a true and accurate copy of the foregoing was served by operation of this Court's electronic filing system on the day of filing to all counsel of record.

/s/ *Henry G. Appel*
HENRY G. APPEL (0068479)
Principal Assistant Attorney General

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

County of Lake, Ohio v. Purdue Pharma L.P., et al.,
Case No. 18-op-45032

County of Trumbull, Ohio v. Purdue Pharma, L.P., et al.,
Case No. 18-op-45079

MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster

PHARMACY DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION TO COMPEL LIMITED ADDITIONAL DATA FROM THE OHIO BOARD OF PHARMACY'S OARRS DATABASE

Exhibit D

The Board of Pharmacy's response to the Pharmacy Defendants' motion to compel OARRS data in Track 3 (a motion the Court granted in Track 1B, Dkt. 3168) continues to miss the mark in three critical ways.

First, the Board's argument relies on the misconception that some legal privilege applies to the limited data the pharmacies seek from OARRS, but it never states what that privilege might be. The Board cites cases (e.g., Opp. at 6) where litigants invoked the physician-patient privilege, the marital privilege, and a statutory mediation privilege, among others, but none of those privileges applies here. The Board offers no argument whatsoever for the application of ***any*** substantive legal privilege. To the extent the Board means to suggest that its statutory confidentiality claims are somehow equivalent to a substantive privilege claim, the Board has not made—and cannot make—any such showing. "[C]onfidentiality is not the same as privilege." *S.E.C. v. McCabe*, 2015 WL 2452937, at *5 (D. Utah May 22, 2015).[1]

Moreover, as the Board is well aware, the Pharmacy Defendants do not seek patient names, addresses, birthdates, or any other protected patient information. The only data the Pharmacy Defendants seek are the prescribers and pharmacies associated with the relevant prescriptions in the OARRS database.[2] Therefore, the state and federal laws the Board relies upon—which are premised entirely on the concern that disclosure of data would allow identification of patients—do not apply. They certainly do not justify the Board's refusal to produce the data.

[1] The Board's confidentiality arguments also ignore the fact that, in 2019, a wide variety of people accessed OARRS more than 240 million times, including thousands of healthcare providers, professional licensing boards, law enforcement personnel, drug court personnel, and hospital peer review committees. *See* OARRS 2019 Annual Report at 2, 3, 10, available at https://www.ohiopmp.gov/documents/Annual%20Report%20(2019).pdf.

[2] The Board asserts that the pharmacies seek pharmacy and prescriber information for ***all*** prescriptions in the OARRS database. (Opp. at 10.) That is not correct. The Pharmacy Defendants' Track 3 subpoena is limited to prescriptions for a specific list of medications, the same list that the Court has ordered the pharmacies to produce from their own data. Testosterone, Ambien, and Ritalin, for example, are not on that list.

The Board's confidentiality concerns are properly addressed by ordering production pursuant to a protective order, not by the withholding of data that is critical to the Pharmacy Defendants' defense. The Court has repeatedly ordered the pharmacies to produce the very same data from their own databases for the entire state of Ohio. *See* Dkt. 2976, Dkt. 3055, Dkt. 3341. The Court also has ruled that the protective orders in this case are sufficient to protect that data. *See* Dkt. 3055 at 2 ("The Court has put into place numerous protective orders specifically addressing health information protected under the Health Insurance Portability and Accountability Act ('HIPAA'), such as patient prescriptions.").[3]

Second, because there is no privilege claim at issue, there is no need to address whether state or federal law supplies the "rule of decision." The Federal Rules of Civil Procedure—Rule 45, in particular—indisputably govern whether the Board must produce the data in question. The Board has not met its burden to show good cause for resisting the subpoena. In fact, the Board says nothing at all about any burden that would result from having to produce the requested data, effectively conceding that the burden is slight or nonexistent.

Third, the Board continues to misconstrue the nature of the data the Pharmacy Defendants seek, why the pharmacies need it, and what the pharmacies plan to do with it. The pharmacies need to know the prescribers and dispensers associated with the relevant prescriptions in order to identify the doctors and pharmacies that may have actually caused the opioids crisis in Lake and Trumbull Counties as alleged by plaintiffs. This data will ***not*** reveal the identity of any patient and is critical to the pharmacies' defense of alternative causation.

[3] The State of New York produced its PDMP data—including names of doctors and pharmacies associated with prescriptions—in the consolidated New York opioids litigation pursuant to similar protective order provisions. *See* Ex. 1, Keller Tr. 268:20-270:25; Ex. 2, NY Protective Order.

The Board suggests that the Pharmacy Defendants intend to violate the confidentiality of their own patients' sensitive health information in order to "reverse engineer" the identity of patients in the OARRS data. (Opp. at 11.) The accusation is baseless. Just the opposite, the Pharmacy Defendants have fought to ***avoid*** disclosing their patients' protected information, because patient privacy is critical to the Pharmacy Defendants and required by law.

Moreover, the Board ignores the fact that Plaintiffs chose not to sue approximately 42 percent of the dispensing market in Lake and Trumbull Counties. The Pharmacy Defendants do not have any dispensing data from that significant portion of the market. The Pharmacy Defendants' own dispensing data does nothing to fill that gap. Nor does the data that the Board has already produced, as illustrated by the chart at page 12 of the Board's opposition brief:

DateFilled	01/01/2015
RxNumber	123456
RefillCode	0
Quantity	30
DaysSupp	30
NDC	54092038101
Drug	ADDERALL XR 5 MG CER
TherClassCode	2820040010
TherClassDesc	Amphetamine & Comb.
DateWritten	01/01/2015
NumOfRefillsAuth	0
PaymentType	4
PharmacyHash	1111AAAAA11AA1111A11AA1AA11AA1111AAAAA
PharmacyZip	445
PharmacyBACCode	A
PharmacyBACSubCode	3
PrescriberHash[5]	1AA11AA111A1111AA111111AA11A111111AA111A1
PrescriberZip	445
PrescriberBACCode	C
PrescriberBACSubCode	
PrescriberSpecialty	Pediatric medicine
PatientGroupIDHash	A1A1111A11111A11AAAAAAA1AA11111A11111A11A1
PatientAge	8
PatientSex	2
PatientZip	445

The Pharmacy Defendants cannot do anything with this data to identify the doctors and pharmacies who may have contributed to the opioids crisis alleged by plaintiffs.

The Board has nothing to say about other ways the Pharmacy Defendants might obtain this information and does not even respond to the argument that it would be impossible under the Court's schedule to obtain it from the dozens of third-party pharmacies plaintiffs chose not to sue in this litigation. In effect, the Board concedes that OARRS is the only source of the information the Pharmacy Defendants need.

Because the data in question is not protected patient information, because OARRS is the only source of that data, and because the Pharmacy Defendants' "need for the data in this litigation outweighs any countervailing concerns," Dkt. 3168 at 7, the Court should grant the Pharmacy Defendants' motion to compel.

Dated: July 22, 2020

Respectfully submitted,

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I, the undersigned, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record on July 22, 2020.

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EXHIBIT 1

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK
----------X
IN RE OPIOID LITIGATION
Index No: 400000/2017
----------X
This document relates to:
The County of Nassau, New York v.
Purdue Pharma L.P.,
Case No. 400001/2017
----------X
The County of Suffolk, New York v.
Purdue Pharma L.P.,
Case No. 400008/2017
----------X
The People of the State of New York v.
Purdue Pharma L.P.
Case No. 400016/2018
----------X

January 23, 2020
9:20 A.M.

EXAMINATION BEFORE TRIAL of LACEY KELLER, an Expert Witness herein, taken by the attorneys for the respective parties, pursuant to Notice, held at the above-stated time and place, before Melissa Leonetti, RPR, a Notary Public of the State of New York.

break out the Walmart numbers, you aren't planning to offer an opinion about those broken-out Walmart numbers at trial, fair?

A. Correct. Not at this time.

Q. Likewise, for tables like table 52 that offer rolled-up numbers for each county in New York, is it fair to say you are not going to offer an opinion at trial that separates out which of those numbers might be attributed to any particular defendant?

A. As I have not been asked to amend the report beyond what is shown here.

Q. You keep saying you have not been asked to amend your report beyond what it says here --

A. I have no plans, sitting here, to amend this to show it in any other way.

Q. Turn, if you would, please, to page 7.

A. Okay.

Q. Paragraph 13 talks about the New York Department of Health prescription monitoring program data, correct?

A. Correct.

Q. You describe that prescription monitoring data as prescription data that is maintained by the

L. KELLER

New York Department of Health and widely used by prescribers, pharmacies, and law enforcement agencies to track and exchange patient data, correct?

A. Yes. I believe this is a characterization from the PDMP website where they describe the data. But yes, that's what it says here.

Q. And do you understand that to be the truth?

A. Yes, as I've read it on their website.

Q. You also say in paragraph 13 that in 2018 it was estimated that the database contained critical information on approximately 150 million patients in New York and 24 other states. Correct?

A. Correct. And again, I might have been more accurate to put some sort of reference to the PDMP website here to support these citations.

Q. New York's prescription monitoring data includes a variety of information on every prescription for opioids filled in New York going back to roughly 2014; is that fair?

MS. CONROY: Objection.

A. Yes, I believe so.

Q. As you understand that that prescription data was produced in this litigation, correct?

A. Yes. That's why it was made available to me.

Q. As that data was produced in this case, you can't see the patient name, but each patient gets a unique identifying number, correct?

A. I believe that to be correct. There might be an additional identifier of the patient in that data set, maybe a ZIP code, but I can't remember without looking at the data.

Q. Do you understand that the prescription monitoring data that was produced in this case also includes the medication and the dose for each prescription?

A. Yes. It would list what product was being prescribed and as well as the number of dosage units or doses in that prescription, yes.

Q. The prescription data that has been produced in this case also includes the date the prescription was filled, the doctor who wrote it, the pharmacy that filled it?

A. Yes, I believe all of these fields are in there.

EXHIBIT 2

E-FILE

At a IAS Term, Part 48 of the Supreme Court of the State of New York, held in and for the County of Suffolk at Central Islip, New York on the 24th day of Jan 2019

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

IN RE OPIOID LITIGATION

THIS DOCUMENT RELATES TO ALL CASES

Index No. 400000/2017 E

Hon. Jerry Garguilo

PROTECTIVE ORDER

I. Scope of Order

1. Disclosure and discovery activity in this proceeding may involve production of confidential, proprietary, and/or private information for which special protection from public disclosure and from use for any purpose other than prosecuting this litigation would be warranted. Accordingly, the Parties hereby stipulate to and petition the Court to enter the following Stipulated Protective Order ("Protective Order" or "Order"). Unless otherwise noted, this Order is also subject to the local rules of this Court and the New York Civil Practice Law and Rules on matters of procedure and calculation of time periods. Unless otherwise stated, all periods of time provided for in this Order are calculated as calendar days.

2. This Protective Order shall govern all hard copy and electronic materials, the information contained therein, and all other information produced or disclosed during this coordinated proceeding, which includes any related actions that have been or will be transferred to this Court ("the Litigation"), and all materials produced or adduced in the course of discovery, including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response or otherwise, by any Party to this Litigation to any other party or parties. This Protective Order is binding upon all the Parties to this Litigation, including their respective corporate parents, subsidiaries and affiliates and their

respective attorneys, principals, agents, experts, consultants, representatives, directors, officers, and employees, and others as set forth in this Protective Order.

3. Third parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and thereby become a Designating Party for purposes of this Protective Order.

4. The entry of this Protective Order does not preclude any party from seeking a further order of this Court as warranted.

5. Nothing herein shall be construed to affect in any manner the admissibility at trial or any other court proceeding of any document, testimony, or other evidence.

6. This Protective Order does not confer blanket protection on all disclosures or responses to discovery and the protection it affords extends only to the specific information or items that are entitled to protection under the applicable legal principles for treatment as confidential.

II. Definitions

7. Party. "Party" means any of the parties in this Litigation at the time this Protective Order is entered, including officers and directors of such parties. If additional parties are added other than parents, subsidiaries or affiliates of current parties to this Litigation, then their ability to receive Confidential Information and/or Highly Confidential Information as set forth in this Protective Order will be subject to them being bound, by agreement or Court Order, to this Protective Order.

8. Discovery Material. "Discovery Material" means any information, document, or tangible thing, response to discovery requests, deposition testimony or transcript, and any other similar materials, or portions thereof. To the extent that matter stored or recorded in the form of electronic or magnetic media (including information, files, databases, or programs stored on any

digital or analog machine-readable device, computers, Internet sites, discs, networks, or tapes) ("Computerized Material") is produced by any Party in such form, the Designating Party may designate such matters as confidential by a designation of "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" on the media. Whenever any Party to whom Computerized Material designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL is produced reduces such material to hardcopy form, that Party shall mark the hardcopy form with the corresponding "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" designation.

9. Competitor. Competitor means any company or individual, other than the Designating Party, engaged in the design; development; manufacture; regulatory review process; dispensing; marketing; distribution; creation, prosecution, pursuit, or other development of an interest in protecting intellectual property; and/or licensing of any product or services involving opioids; provided, however, that this section shall not be construed as limiting the disclosure of Discovery Material to an Expert in this Litigation, so long as the notice required under Paragraph 34 is provided to the Designating Party prior to any such disclosure where required, and so long as no Discovery Material produced by one Defendant is shown to any current employee or consultant of a different Defendant, except as provided in Paragraphs 29 or 30.

10. Confidential Information. "Confidential Information" is defined herein as information that the Designating Party in good faith believes would be entitled to protection on a motion for a protective order on the basis that it constitutes, reflects, discloses, or contains information protected from disclosure by statute or that should be protected from disclosure as confidential personal information, medical or psychiatric information, personnel records, Confidential Protected Health Information, protected law enforcement materials (including investigative files, overdose records, narcane, coroner's records, court records, and prosecution

files), research, technical, commercial or financial information that the Designating Party has maintained as confidential, or such other proprietary or sensitive business and commercial information that is not publicly available. In addition, to the extent that a Designating Party produces discovery materials in this action designated as "Confidential" in *In re National Prescription Opioids Litigation*, Case No. 17-MD-2804 (N.D. Ohio), those discovery materials shall be deemed to be "Confidential Information" under this Protective Order. Public records and other information or documents that are publicly available may not be designated as Confidential Information. In designating discovery materials as Confidential Information, the Designating Party shall do so in good faith consistent with the provisions of this Protective Order and rulings of the Court. Nothing herein shall be construed to allow for global designations of all documents as "Confidential."

11. Highly Confidential Information. "Highly Confidential Information" is defined herein as information which, if disclosed, disseminated, or used by or to a Competitor of the Designating Party or any other person not enumerated in Paragraphs 29 and 30, could reasonably result in possible antitrust violations or commercial, financial, or business harm. In addition, to the extent that a Designating Party produces discovery materials in this action designated as "Highly Confidential" in *In re National Prescription Opioids Litigation*, Case No. 17-MD-2804 (N.D. Ohio), those discovery materials shall be deemed to be "Highly Confidential Information" under this Protective Order. In designating discovery materials as Highly Confidential Information, the Designating Party shall do so in good faith consistent with the provisions of this Protective Order and rulings of the Court. Nothing herein shall be construed to allow for global designations of all documents as "Highly Confidential."

12. Receiving Party. "Receiving Party" means a Party to this Litigation, and all employees, agents, and directors (other than Counsel) of the Party that receives Discovery Material from a Designating Party.

13. Designating Party. "Designating Party" means a Party to this Litigation, and all directors, employees, and agents (other than Counsel) of the Party, or any third party that produces or otherwise makes available Discovery Material to a Receiving Party, subject to Paragraph 3, or that designates Discovery Material (whether produced by the Designating Party or another party or entity) as Confidential or Highly Confidential.

14. Protected Material. "Protected Material" means any Discovery Material, and any copies, abstracts, summaries, or information derived from such Discovery Material, and any notes or other records regarding the contents of such Discovery Material, that is designated as "Confidential" or "Highly Confidential" in accordance with this Protective Order.

15. Outside Counsel. "Outside Counsel" means any law firm or attorney who represents any Party for purposes of this litigation.

16. In-House Counsel. "In-House Counsel" means attorney employees of any Party.

17. Counsel. "Counsel," without another qualifier, means Outside Counsel and In-House Counsel.

18. Independent Expert. "Independent Expert" means an expert and/or independent consultant formally retained, and/or employed to advise or to assist Counsel in the preparation and/or trial of this Litigation, and their staff who are not employed by a Party to whom it is reasonably necessary to disclose Confidential Information or Highly Confidential Information for the purpose of this Litigation.

III. Designation and Redaction of Confidential Information

19. For each document produced by the Designating Party that contains or constitutes Confidential Information or Highly Confidential Information pursuant to this Protective Order, each page shall be marked "CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER", or "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" or comparable notices.

20. Specific discovery responses produced by the Designating Party shall, if appropriate, be designated as Confidential Information or Highly Confidential Information by marking the pages of the document that contain such information with the notation "CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER", or "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" or comparable notices.

21. Information disclosed through testimony at a deposition taken in connection with this Litigation may be designated as Confidential Information or Highly Confidential Information by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days of the Designating Party's receipt of the certified transcript of a deposition. The court reporter will indicate the portions designated as Confidential or Highly Confidential and segregate them as appropriate. Designations of transcripts will apply to audio, video, or other recordings of the testimony. The court reporter shall clearly mark any transcript released prior to the expiration of the 30-day period as "HIGHLY CONFIDENTIAL—SUBJECT TO FURTHER CONFIDENTIALITY REVIEW." Such transcripts will be treated as Highly Confidential Information until the expiration of the 30-day period. If the Designating Party does not serve a designation letter within the 30-day period, then the entire transcript will be deemed not to contain Confidential Information or Highly Confidential Information and the "HIGHLY CONFIDENTIAL—SUBJECT TO FURTHER CONFIDENTIALITY REVIEW" legend shall be removed.

22. In accordance with this Protective Order, only the persons identified under Paragraphs 29 and 30, below, along with the witness and the witness's counsel may be present if any questions regarding Confidential Information or Highly Confidential are asked. This paragraph shall not be deemed to authorize disclosure of any document or information to any person to whom disclosure is prohibited under this Protective Order.

23. A Designating Party in this Litigation may designate as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" any document, material, or other information produced by, or testimony given by, any other person or entity that the Designating Party reasonably believes qualifies as the Designating Party's Confidential Information or Highly Confidential Information pursuant to this Protective Order. The Designating Party shall designate the information as such within thirty (30) days of receipt of such information. Any Party receiving information from a third party shall treat such information as Highly Confidential during this thirty (30) day period while all Parties have an opportunity to review the information and determine whether it should be designated as confidential. Any Party designating third party information as Confidential Information or Highly Confidential Information shall have the same rights as a Designating Party under this Protective Order with respect to such information.

24. This Protective Order shall not be construed to protect from production or to permit the "Confidential Information" or "Highly Confidential Information" designation of any document that (a) the party has not made reasonable efforts to keep confidential, or (b) is at the time of production or disclosure, or subsequently becomes, through no wrongful act on the part of the Receiving Party or the individual or individuals who caused the information to become public, generally available to the public through publication or otherwise.

25. In order to protect against unauthorized disclosure of Confidential Information and Highly Confidential Information, a Designating Party may redact certain Confidential or Highly Confidential Information from produced documents, materials or other things. The basis for any such redaction shall be stated in the Redaction field of the metadata produced pursuant to the Document Production Protocol or, in the event that such metadata is not technologically feasible, a log of the redactions. Specifically, the Designating Party may redact:

i. Personal Identifying Information. The names, home addresses, personal email addresses, home telephone numbers, Social Security or tax identification numbers, and other private information protected by law of (a) current and former employees (other than employees' names and business contact information) and (b) individuals in clinical studies or adverse event reports whose identity is protected by law.

ii. Privileged Information. Information protected from disclosure by the attorney-client privilege, work product doctrine, or other such legal privilege protecting information from discovery in this Litigation. The obligation to provide, and form of, privilege logs will be addressed by separate Order.

iii. Third Party Confidential Information. If agreed to by the Parties or ordered by the Court under Paragraph 74, information that is protected pursuant to confidentiality agreements between Designating Parties and third parties, as long as the agreements require Designating Parties to redact such information in order to produce such documents in litigation.

26. To the extent any document, materials, or other things produced contain segregated, non-responsive Confidential or Highly Confidential Information concerning a Designating Party's non-opioid products (or, in the case of Plaintiffs, concerning programs,

services, or agencies not at issue in this litigation), the Designating Party may redact that segregated, non-responsive, Confidential or Highly Confidential information except (a) that if a Designating Party's non-opioid product is mentioned in direct comparison to the Designating Party's opioid product, then the name and information about that product may not be redacted or (b) if the redaction of the name and information about the Designating Party's non-opioid product(s) would render the information pertaining to Designating Party's opioid product meaningless or would remove the context of the information about Designating Party's opioid product, the name and information about the other product may not be redacted. Nothing in this paragraph shall restrict Plaintiffs' right and ability to request information about such other products nor restrict Defendants' right to object to or otherwise seek protection from the Court concerning any such request.

27. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients who were reported as experiencing adverse events that are not redacted shall be treated as confidential, regardless of whether the document containing such names is designated as CONFIDENTIAL INFORMATION. No such person shall be contacted, either directly or indirectly, based on the information so disclosed without the express written permission of the Designating Party.

IV. Access to Confidential and Highly Confidential Information

28. General. The Receiving Party and counsel for the Receiving Party shall not disclose or permit the disclosure of any Confidential or Highly Confidential Information to any third person or entity except as set forth in Paragraphs 29 and 30.

29. In the absence of written permission from the Designating Party or an order of the Court, any Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by

Case 1:17-md-02804-DAP Doc #: 3421-21 Filed: 08/22/20 11 of 38 160. PageID #: 499349

Paragraph 29.l) and its contents shall not be disclosed to any person unless that person falls within at least one of the following categories:

a. Outside Counsel and In-House Counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel;

b. Vendor agents retained by the Parties or counsel for the Parties, provided that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;

c. Individual Parties;

d. Present or former officers, directors, and employees of a Party, provided that former officers, directors, or employees of the Designating Party may be shown documents prepared after the date of his or her departure only to the extent counsel for the Receiving Party determines in good faith that the employee's assistance is reasonably necessary to the conduct of this Litigation and provided that such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Nothing in this paragraph shall be deemed to permit the showing of one defendant's Confidential Information to an officer, director, or employee of another defendant, except to the extent otherwise authorized by this Order;

e. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;

f. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;

g. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;

h. Any individual(s) who authored, prepared, or previously reviewed or received the information;

i. Those liability insurance companies from which any Defendant has sought or may seek insurance coverage to (i) provide or reimburse for the defense of the Litigation and/or (ii) satisfy all or part of any liability in the Litigation, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;

j. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the Designating Party may request a meet and confer and may seek a protective order from the Court. The Office of the

Attorney General is exempt from the requirement to give notice of intent to disclose;

k. Plaintiff's counsel of record to any Plaintiff with a case pending in Suffolk County, New York, In Re Opioid Litigation, Index No. 400000/2017 shall be permitted to receive the Confidential Information of any Designating Party regardless of whether that attorney is counsel of record in any individual action against the Designating Party and there shall be no need for such counsel to execute such acknowledgement because such counsel is bound by the terms of this Protective Order;

l. Counsel for claimants in litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, or distribution of opioid products for use in this or such other action in which the Designating Party is a Defendant in that litigation, provided that the proposed recipient agrees to be bound by this Protective Order and completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgements and will receive Confidential and Highly Confidential Information pursuant to this Order and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant

represented by counsel in such outside litigation, to the jurisdiction of this Court or a waiver of any jurisdictional arguments available to such claimant, provided, however, that any such recipient of documents or information produced under this Order shall submit to the jurisdiction of this Court for any violations of this Order; or

m. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order. A Party wishing to use as a deposition exhibit a document produced in native format and designated as Confidential Information shall ensure that the marked deposition exhibit also includes the slip sheet produced as an associated TIFF file bearing the production number assigned to that native-file document and the confidentiality designation made for that document.

30. In the absence of written permission from the Designating Party or an order of the Court, any Highly Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 30.j) and its contents shall not be disclosed to any person unless that person falls within at least one of the following categories:

a. Outside Counsel and In-House Counsel of any Plaintiff, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel.

Information designated as Highly Confidential by any Defendant may be disclosed to one In-House counsel of another Defendant, provided that the In-House counsel (i) has regular involvement in the Litigation, (ii) disclosure to the individual is reasonably necessary to this Litigation, and (iii) the individual completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Except as otherwise provided in this Order or any other Order in this Litigation, no other Employees of a Defendant may receive the Highly Confidential information of another. Any information designated as Highly Confidential shall be disclosed to an In-House Counsel for any Plaintiff only to the extent Outside Counsel for that Plaintiff determines in good faith that disclosure to the In- House Counsel is reasonably necessary to the Litigation;

b. Vendor agents retained by the Parties or counsel for the Parties, provided that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;

c. Individual Parties that have produced the designated information;

d. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;

e. The Court, any Special Referee appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;

f. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;

g. Any individual(s) who authored, prepared or previously reviewed or received the information;

h. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the Designating Party may request a meet and confer and may seek a protective order from the Court. The Office of the Attorney General is exempt from the requirement to give notice of intent to disclose;

i. Plaintiff's counsel of record to any Plaintiff with a case pending in Suffolk County, New York, In Re Opioid Litigation, Index No. 400000/2017 shall be permitted to receive the Confidential Information of any Designating Party regardless of whether that attorney is counsel of record in any individual action against the Designating Party and there shall be no need for such counsel to execute such acknowledgement because such counsel is bound by the terms of this Protective Order;

j. Counsel for claimants litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, or distribution of opioid products for use in this or such other action in which the Designating Party is a Defendant in that litigation, provided that the proposed recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgements and will receive Confidential and Highly Confidential Information pursuant to this Order and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or a waiver of any jurisdictional arguments available to such claimant, provided, however, that any such recipient of documents or information produced under this Order shall submit to the jurisdiction of this Court for any violations of this Order; or

k. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Highly Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Highly Confidential Information of one defendant may be

shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order. A Party wishing to use as a deposition exhibit a document produced in native format and designated as Highly Confidential Information shall ensure that the marked deposition exhibit also includes the slip sheet produced as an associated TIFF file bearing the production number assigned to that native-file document and the confidentiality designation made for that document.

31. With respect to documents produced to Plaintiffs, documents designated as "HIGHLY CONFIDENTIAL" will be treated in the same manner as documents designated "CONFIDENTIAL," except that Plaintiffs may not disclose Highly Confidential Information to In-House Counsel (or current employees) of any Competitor of the Designating Party, except as otherwise provided in this Order or any other Order in this Litigation.

32. In the event that In-House Counsel (or current employees) of any Competitor of the Designating Party is present at the deposition of an employee or former employee of the Designating Party, prior to a document designated as Highly Confidential being used in the examination, such In-House Counsel (and current employees) of any Competitor of the Designating Party shall excuse himself or herself from the deposition room without delaying or disrupting the deposition.

V. Confidentiality Acknowledgment

33. Each person required under this Order to complete the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound, shall be provided with a copy of this Protective Order, which he or she shall read, and, upon reading this Protective Order, shall sign an Acknowledgment, in the form annexed hereto as Exhibit A, acknowledging that he or she has

read this Protective Order and shall abide by its terms. These Acknowledgments are strictly confidential. Unless otherwise provided in this Order, Counsel for each Party shall maintain the Acknowledgments without giving copies to the other side. The Parties expressly agree, and it is hereby ordered that, except in the event of a violation of this Protective Order, there will be no attempt to seek copies of the Acknowledgments or to determine the identities of persons signing them. If the Court finds that any disclosure is necessary to investigate a violation of this Protective Order, such disclosure will be pursuant to separate court order. Persons who come into contact with Confidential Information or Highly Confidential Information for clerical or administrative purposes, and who do not retain copies or extracts thereof, are not required to execute Acknowledgements, but must comply with the terms of this Protective Order.

VI. Litigation Experts and Consultants.

34. Formally Retained Independent Experts and Consultants. Subject to the provisions of this Protective Order, all Confidential Information or Highly Confidential Information may be disclosed to any formally retained independent expert or consultant who has agreed in writing pursuant to Paragraph 33 or on the record of a deposition to be bound by this Protective Order. The party retaining an independent expert or consultant shall use diligent efforts to determine if the independent expert or consultant is currently working with or for a Competitor of a Designating Party in connection with a Competitor's opioid product. Prior to the initial disclosure of any information designated as Confidential Information or Highly Confidential Information to an expert or consultant who is currently working with or for a Competitor of the Designating Party in connection with a Competitor's opioid product, the party wishing to make such a disclosure ("Notifying Party") shall provide to counsel for the Designating Party in writing, which may include by e-mail, a statement that such disclosure will be made, identifying the general subject matter category of the Discovery Material to be

disclosed, providing the nature of the affiliation with the Competitor entity and name of the Competitor entity, and stating the general purpose of such disclosure; the specific name of the formally retained independent expert or consultant need not be provided. The Designating Party shall have seven (7) days from its receipt of the notice to deliver to the Notifying Party its good faith written objections (if any), which may include e-mail, to such disclosure to the expert or consultant.

35. Absent timely objection, the expert or consultant shall be allowed to receive Confidential and Highly Confidential Information pursuant to the terms of this Protective Order. Upon and pending resolution of a timely objection, disclosure to the expert or consultant shall not be made. If the Notifying Party desires to challenge the Designating Party's written objection to the expert or consultant, the Notifying Party shall inform the Designating Party in writing, within ten (10) days of receipt of the Designating Party's written objection, of its reasons for challenging the objection. The expert or consultant shall then be allowed to receive Confidential and Highly Confidential Information pursuant to the terms of this Protective Order after seven (7) days from receipt of the Designating Party's timely challenge to the written objection to the expert or consultant, unless within that seven day period, the Designating Party seeks relief from the Court pursuant to the procedures for discovery disputes set forth in Case Management Order No. 2, or the Parties stipulate to an agreement. Once a motion is filed, disclosure shall not occur until the issue is decided by the Court and, if the motion is denied, the appeal period from the Court order denying the motion has expired. In making such motion, it shall be the Designating Party's burden to demonstrate good cause for preventing such disclosure.

VII. Protection and Use of Confidential and Highly Confidential Information

36. Persons receiving or having knowledge of Confidential Information or Highly Confidential Information by virtue of their participation in this proceeding, or by virtue of obtaining any documents or other Protected Material produced or disclosed pursuant to this Protective Order, shall use that Confidential Information or Highly Confidential Information only as permitted by this Protective Order. Counsel shall take reasonable steps to assure the security of any Confidential Information or Highly Confidential Information and will limit access to such material to those persons authorized by this Protective Order.

37. Nothing herein shall restrict a person qualified to receive Confidential Information and Highly Confidential Information pursuant to this Protective Order from making working copies, abstracts, digests and analyses of such information for use in connection with this Litigation and such working copies, abstracts, digests and analyses shall be deemed to have the same level of protection under the terms of this Protective Order. Further, nothing herein shall restrict a qualified recipient from converting or translating such information into machine-readable form for incorporation in a data retrieval system used in connection with this Litigation, provided that access to such information, in whatever form stored or reproduced, shall be deemed to have the same level of protection under the terms of this Protective Order.

38. All persons qualified to receive Confidential Information and Highly Confidential Information pursuant to this Protective Order shall at all times keep all notes, abstractions, or other work product derived from or containing Confidential Information or Highly Confidential Information in a manner to protect it from disclosure not in accordance with this Protective Order, and shall be obligated to maintain the confidentiality of such work product and shall not disclose or reveal the contents of said notes, abstractions or other work product after the documents, materials, or other thing, or portions thereof (and the information contained therein)

are returned and surrendered pursuant to Paragraph 45. Nothing in this Protective Order requires the Receiving Party's Counsel to disclose work product at the conclusion of the case.

39. Notwithstanding any other provisions hereof, nothing herein shall restrict any Party's Counsel from rendering advice to that Counsel's clients with respect to this proceeding or a related action in which the Receiving Party is permitted by this Protective Order to use Confidential Information or Highly Confidential Information and, in the course thereof, relying upon such information, provided that in rendering such advice, Counsel shall not disclose any other Party's Confidential Information or Highly Confidential Information other than in a manner provided for in this Protective Order.

40. Nothing contained in this Protective Order shall prejudice in any way the rights of any Party to object to the relevancy, authenticity, or admissibility into evidence of any document or other information subject to this Protective Order, or otherwise constitute or operate as an admission by any Party that any particular document or other information is or is not relevant, authentic, or admissible into evidence at any deposition, at trial, or in a hearing.

41. Nothing contained in this Protective Order shall preclude any Party from using its own Confidential Information or Highly Confidential Information in any manner it sees fit, without prior consent of any Party or the Court.

42. To the extent that a Designating Party uses or discloses to a third party its designated confidential information in a manner that causes the information to lose its confidential status, the Receiving Party is entitled to notice of the Designating Party's use of the confidential information in such a manner that the information has lost its confidentiality, and the Receiving Party may also use the information in the same manner as the Designating Party.

43. If a Receiving Party learns of any unauthorized disclosure of Confidential Information or Highly Confidential Information, it shall immediately (a) inform the Designating Party in writing of all pertinent facts relating to such disclosure; (b) make its best effort to retrieve all copies of the Confidential Information or Highly Confidential Information; (c) inform the person or persons to whom unauthorized disclosures were made of all the terms of this Protective Order; and (d) request such person or persons execute the Acknowledgment that is attached hereto as Exhibit A.

44. Unless otherwise agreed or ordered, this Protective Order shall remain in force after dismissal or entry of final judgment not subject to further appeal of this Litigation.

45. Within ninety (90) days after dismissal or entry of final judgment not subject to further appeal of this Litigation, or such other time as the Designating Party may agree in writing, the Receiving Party shall return all Confidential Information and Highly Confidential Information under this Protective Order unless: (1) the document has been offered into evidence or filed without restriction as to disclosure; (2) the Parties agree to destruction to the extent practicable in lieu of return;[1] or (3) as to documents bearing the notations, summations, or other mental impressions of the Receiving Party, that Party elects to destroy the documents and certifies to the Designating Party that it has done so.

46. Notwithstanding the above requirements to return or destroy documents, Plaintiffs' outside counsel and Defendants' outside counsel may retain (1) any materials required to be retained by law or ethical rules, (2) one copy of their work file and work product, and (3)

[1] The Parties may choose to agree that the Receiving Party shall destroy documents containing Confidential Information or Highly Confidential Information and certify the fact of destruction, and that the Receiving Party shall not be required to locate, isolate and return e-mails (including attachments to e-mails) that may include Confidential Information or Highly Confidential Information, or Confidential Information or Highly Confidential Information contained in deposition transcripts or drafts or final expert reports.

one complete set of all documents filed with the Court including those filed under seal, deposition and trial transcripts, and deposition and trial exhibits. Any retained Confidential or Highly Confidential Discovery Material shall continue to be protected under this Protective Order. An attorney may use his or her work product in subsequent litigation, provided that the attorney's use does not disclose or use Confidential Information or Highly Confidential Information.

VIII. Changes in Designation of Information

47. If a Party through inadvertence produces any Confidential Information or Highly Confidential Information without labeling or marking or otherwise designating it as such in accordance with the provisions of this Protective Order, the Designating Party may give written notice to the Receiving Party that the document or thing produced is deemed "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" and should be treated as such in accordance with the provisions of this Protective Order, and provide replacement media, images, and any associated production information to conform the document to the appropriate designation and facilitate use of the revised designation in the production. The Receiving Party must treat such documents and things with the noticed level of protection from the date such notice is received. Disclosure, prior to the receipt of such notice of such information, to persons not authorized to receive such information shall not be deemed a violation of this Protective Order. Any Designating Party may designate as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" or withdraw a "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" designation from any material that it has produced consistent with this Protective Order, provided, however, that such redesignation shall be effective only as of the date of such redesignation. Such redesignation shall be accomplished by notifying Counsel for each Party in writing of such redesignation and providing replacement images bearing the appropriate

description, along with the replacement media, images, and associated production information referenced above. Upon receipt of any redesignation and replacement image that designates material as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL", the Receiving Party shall (i) treat such material in accordance with this Protective Order; (ii) take reasonable steps to notify any persons known to have possession of any such material of such redesignation under this Protective Order; and (iii) promptly endeavor to procure all copies of such material from any persons known to have possession of such material who are not entitled to receipt under this Protective Order. It is understood that the Receiving Party's good faith efforts to procure all copies may not result in the actual return of all copies of such materials.

48. A Receiving Party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed. If the Receiving Party believes that portion(s) of a document are not properly designated as Confidential Information or Highly Confidential Information, the Receiving Party will identify the specific information that it believes is improperly designated and notify the Designating Party, in writing or voice-to-voice dialogue, of its good faith belief that the confidentiality designation was not proper and must give the Designating Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain, in writing within seven (7) days, the basis of the chosen designation. If a Receiving Party elects to press a challenge to a confidentiality designation after considering the justification offered by the Designating Party, it shall notify the Designating Party and the Receiving Party shall have seven (7) days from such notification to challenge the designation by commencing a discovery dispute under the procedures set forth in Case Management Order No. 2. The ultimate burden of persuasion in any such challenge proceeding shall be on the

Designating Party as if the Designating Party were seeking a Protective Order in the first instance. Until the Court rules on the challenge, all Parties shall continue to afford the material in question the level of protection to which it is entitled under the Designating Party's designation. In the event that a designation is changed by the Designating Party or by Court Order, the Designating Party shall provide replacement media, images, and associated production information as provided above.

IX. Inadvertent Production of Documents

49. Non-Waiver of Privilege. The Parties agree that they do not intend to disclose information subject to a claim of attorney-client privilege, attorney work product protection, common-interest privilege, or any other privilege, immunity or protection from production or disclosure ("Privileged Information"). If, nevertheless, a Designating Party discloses Privileged Information, such disclosure (as distinct from use) shall be deemed inadvertent without need of further showing and shall not constitute or be deemed a waiver or forfeiture of the privilege or protection from discovery in this case or in any other federal or state proceeding by that party (the "Disclosing Party"). This Section shall be interpreted to provide the maximum protection allowed under applicable laws.

50. Notice of Production of Privileged Information. If a Party or non-Party discovers that it has produced Privileged Information, it shall promptly notify the Receiving Party of the production in writing, shall identify the produced Privileged Information by Bates range where possible, and may demand that the Receiving Party return or destroy the Privileged Information. In the event that a Receiving Party receives information that it believes is subject to a good faith claim of privilege by the Designating Party, the Receiving Party shall immediately refrain from examining the information and shall promptly notify the Designating Party in writing that the Receiving Party possesses potentially Privileged Information. The Designating Party shall have

seven (7) days to assert privilege over the identified information. If the Designating Party does not assert a claim of privilege within the 7-day period, the information in question shall be deemed non-privileged.

51. Recall of Privileged Information. If the Designating Party has notified the Receiving Party of production of Privileged Information, or has confirmed the production of Privileged Information called to its attention by the Receiving Party, the Receiving Party shall within fourteen (14) days of receiving such notification or confirmation: (1) destroy or return to the Designating Party all copies or versions of the produced Privileged Information requested to be returned or destroyed; (2) delete from its work product or other materials any quoted or paraphrased portions of the produced Privileged Information; and (3) ensure that produced Privileged Information is not disclosed in any manner to any Party or non-party. The following procedures shall be followed to ensure all copies of such ESI are appropriately removed from the Receiving Party's system:

i. Locate each recalled document in the document review/production database and delete the record from the database;

ii. If there is a native file link to the recalled document, remove the native file from the network path;

iii. If the database has an image load file, locate the document image(s) loaded into the viewing software and delete the image file(s) corresponding to the recalled documents. Remove the line(s) corresponding to the document image(s) from the image load file;

iv. Apply the same process to any additional copies of the document or database, where possible;

v. Locate and destroy all other copies of the document, whether in electronic or hardcopy form. To the extent that copies of the document are contained on write-protected media, such as CDs or DVDs, these media shall be discarded, with the exception of production media received from the recalling party, which shall be treated as described herein;

vi. If the document was produced in a write-protected format, the party seeking to recall the document shall, at its election, either (i) provide a replacement copy of the relevant production from which the document has been removed, in which case the Receiving Party shall discard the original production media; or (ii) allow the Receiving Party to retain the original production media, in which case the Receiving Party shall take steps to ensure that the recalled document will not be used; and

vii. Confirm that the recall of ESI under this procedure is complete by way of letter to the party seeking to recall ESI.

52. Notwithstanding the above, the Receiving Party may segregate and retain one copy of the clawed back information solely for the purpose of disputing the claim of privilege. The Receiving Party shall not use any produced Privileged Information in connection with this Litigation or for any other purpose other than to dispute the claim of privilege. The Receiving Party may file a motion disputing the claim of privilege and seeking an order compelling production of the material at issue; the Designating Party may oppose any such motion, including on the grounds that inadvertent disclosure does not waive privilege.

53. Within 14 days of the notification that such Privileged Information has been returned, destroyed, sequestered, or deleted ("Clawed-Back Information"), the Disclosing Party shall produce a privilege log with respect to the Clawed-Back Information. Within 14 days after receiving the Disclosing Party's privilege log with respect to such Clawed-Back Information, a

Receiving Party may notify the Disclosing Party in writing of an objection to a claim of privilege or work-product protection with respect to the Clawed-Back Information. Within 14 days of the receipt of such notification, the Disclosing Party and the objecting party shall meet and confer in an effort to resolve any disagreement concerning the Disclosing Party's privilege or work-product claim with respect to such Clawed-Back Information. The Parties may stipulate to extend the time periods set forth in this paragraph.

54. If, for any reason, the Disclosing Party and Receiving Party (or Parties) do not resolve their disagreement after conducting the mandatory meet and confer, the Receiving Party may request a conference with the Court pursuant to the procedures set forth in Case Management Order No. 2. The Disclosing Party bears the burden of establishing the privileged or protected nature of any Privileged Information.

55. Nothing contained herein is intended to or shall serve to limit a Party's right to conduct a review of documents, ESI or information (including metadata) for relevance, responsiveness and/or segregation of privileged and/or protected information before production. Nothing in this Order shall limit the right to request an in-camera review of any Privileged Information.

56. In the event any prior order or agreement between the Parties and/or between the Parties and a non-party concerning the disclosure of privileged and/or work product protected materials conflicts with any of the provisions of this Order, the provisions of this Stipulated Order shall control.

57. Nothing in this Order overrides any attorney's ethical responsibilities to refrain from examining or disclosing materials that the attorney knows or reasonably should know to be privileged and to inform the Disclosing Party that such materials have been produced.

X. Filing and Use at Trial of Protected Material

58. Only Confidential or Highly Confidential portions of relevant documents are subject to sealing. To the extent that a brief, memorandum, or pleading references any document designated as Confidential or Highly Confidential, then the brief, memorandum or pleading shall refer the Court to the particular exhibit filed under seal without disclosing the contents of any Confidential Information. If, however, the Confidential or Highly Confidential Information must be intertwined within the text of the document, a Party may timely move the Court for leave to file both a redacted version for the public docket and an unredacted version for sealing.

59. Any and all filings made under seal shall be submitted according to the Court's applicable rules and procedures and any subsequent Orders issued by the Court. If both redacted and unredacted versions are being submitted for filing, each version shall be clearly named so there is no confusion as to why there are two entries on the docket for the same filing.

60. If the Court requests, a sealed filing shall be placed in a sealed envelope marked "CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER." The sealed envelope shall display the case name and number, a designation as to what the document is, the name of the Party on whose behalf it is submitted, and the name of the attorney who has filed the sealed document. A copy of this Stipulated Protective Order, or other relevant authorizing order, shall be included in the sealed envelope.

61. A Party that intends to present Confidential Information or Highly Confidential Information at a hearing shall bring that issue to the Court's and Parties' attention without disclosing the Confidential Information or Highly Confidential Information. The Court may thereafter make such orders, including any stipulated orders, as are necessary to govern the use of Confidential Information or Highly Confidential Information at the hearing. The use of any

Confidential Information or Highly Confidential Information at trial shall be governed by a separate stipulation and/or court order.

XI. Information or Highly Confidential Information Requested by Third Party; Procedure Following Request.

62. If any person receiving Discovery Material covered by this Protective Order (the "Receiver") is served with a subpoena, a request for information, or any other form of legal process that purports to compel disclosure of any Confidential Information or Highly Confidential Information covered by this Protective Order ("Request"), the Receiver must so notify the Designating Party, in writing, immediately and in no event more than five (5) court days after receiving the Request. Such notification must include a copy of the Request.

63. The Receiver also must immediately inform the party who made the Request ("Requesting Party") in writing that some or all the requested material is the subject of this Protective Order. In addition, the Receiver must deliver a copy of this Protective Order promptly to the Requesting Party.

64. The purpose of imposing these duties is to alert the interested persons to the existence of this Protective Order and to afford the Designating Party in this case an opportunity to protect its Confidential Information or Highly Confidential Information. The Designating Party shall bear the burden and the expense of seeking protection of its Confidential Information or Highly Confidential Information, and nothing in these provisions should be construed as authorizing or encouraging the Receiver in this Litigation to disobey a lawful directive from another court. The obligations set forth in this paragraph remain in effect while the Receiver has in its possession, custody or control Confidential Information or Highly Confidential Information by the other Party in this Litigation.

65. Materials that have been designated as Confidential or Highly Confidential Discovery Material shall not be provided or disclosed to any third party in response to a request under any public records act, or any similar federal, state or municipal law (collectively, the "Public Disclosure Laws"), and are exempt from disclosure pursuant to this Protective Order. If a Party to this Litigation receives such a request, it shall (i) provide a copy of this Protective Order to the Requesting Party and inform it that the requested materials are exempt from disclosure and that the Party is barred by this Protective Order from disclosing them, and (ii) promptly inform the Designating Party that has produced the requested material that the request has been made, identifying the name of the Requesting Party and the particular materials sought. If the Designating Party seeks a protective order, the Receiving Party shall not disclose such material until the Court has ruled on the request for a protective order. The restrictions in this paragraph shall not apply to materials that (i) the Designating Party expressly consents in writing to disclose; or (ii) this Court has determined by court order to have been improperly designated as Confidential or Highly Confidential Discovery Material. The provisions of this section shall apply to any entity in receipt of Confidential or Highly Confidential Discovery Material governed by this Protective Order. Nothing in this Protective Order shall be deemed to (1) foreclose any Party from arguing that Discovery Material is not a public record for purposes of the Public Disclosure Laws; (2) prevent any Party from claiming any applicable exemption to the Public Disclosure Laws; or (3) limit any arguments that a Party may make as to why Discovery Material is exempt from disclosure.

XII. HIPAA-Protected Information

66. General. Discovery in this Litigation may involve production of "Protected Health Information" as that term is defined and set forth in 45 C.F.R. § 160.103, for which

special protection from public disclosure and from any purpose other than prosecuting this Action is warranted

67. "Protected Health Information" shall encompass information within the scope and definition set forth in 45 C.F.R. § 160.103 that is provided to the Parties by a covered entity as defined by 45 C.F.R. § 160.103 ("Covered Entities") or by a business associate of a Covered Entity as defined by 45 C.F.R. § 160.103 ("Business Associate") in the course of the Litigation, as well as information covered by the health privacy laws of New York State.

68. Any Party who produces Protected Health Information in this Litigation shall designate such discovery material "Confidential Protected Health Information" in accordance with the provisions of this Protective Order.

69. Unless otherwise agreed between counsel for the Parties, the designation of discovery material as "Confidential Protected Health Information" shall be made at the following times: (a) for documents or things at the time of the production of the documents or things; (b) for declarations, correspondence, expert witness reports, written discovery responses, court filings, pleadings, and other documents, at the time of the service or filing, whichever occurs first; (c) for testimony, at the time such testimony is given by a statement designating the testimony as "Confidential Protected Health Information" made on the record or within thirty (30) days after receipt of the transcript of the deposition. The designation of discovery material as "Confidential Protected Health Information" shall be made in the following manner: (a) on documents, by placing the notation "Confidential Protected Health Information" or similar legend on each page of such document; (b) for tangible things, by placing the notation "Confidential Protected Health Information" on the object or container thereof or if impracticable, as otherwise agreed by the Parties; (c) for declarations, correspondence, expert

witness reports, written discovery responses, court filings, pleadings, and any other documents containing Protected Health Information, by placing the notation "Confidential Protected Health Information" both on the face of such document and on any particular designated pages of such document; and (d) for testimony, by orally designating such testimony as being "Confidential Protected Health Information" at the time the testimony is given or by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days after receipt of the certified transcript of the deposition.

70. Pursuant to 45 C.F.R. § 164.512(e)(1), all Covered Entities and their Business Associates (as defined in 45 C.F.R. § 160.103), or entities in receipt of information from such entities, are hereby authorized to disclose Protected Health Information pertaining to the Litigation to those persons and for such purposes as designated in herein. Further, all Parties that are entities subject to state privacy law requirements, or entities in receipt of information from such entities, are hereby authorized to disclose Protected Health Information pertaining to this Litigation to those persons and for such purposes as designated in herein. The Court has determined that disclosure of such Protected Health Information is necessary for the conduct of proceedings before it and that failure to make the disclosure would be contrary to public interest or to the detriment of one or more Parties to the proceedings.

71. The Parties shall not use or disclose Protected Health Information for any purpose other than the Litigation, including any appeals. The Parties may, inter alia, disclose Protected Health Information to (a) counsel for the Parties and employees of counsel who have responsibility for the Litigation; (b) the Court and its personnel; (c) Court reporters; (d) experts and consultants; and (e) other entities or persons involved in the Litigation.

72. Within sixty (60) days after dismissal or entry of final judgment not subject to further appeal, the Parties, their counsel, and any person or entity in possession of Protected Health Information received pursuant to this Order shall destroy or return to the Covered Entity or Business Associate such Protected Health Information.

73. Nothing in this Order authorizes the Parties to obtain Protected Health Information through means other than formal discovery requests, subpoenas, depositions, pursuant to a patient authorization, or any other lawful process.

XIII. Information Subject to Existing Obligation of Confidentiality Independent of this Protective Order.

74. In the event that a Party is required by a valid discovery request to produce any information held by it subject to an obligation of confidentiality in favor of a third party, the Party shall, promptly upon recognizing that such third party's rights are implicated, provide the third party with a copy of this Protective Order and (i) inform the third party in writing of the Party's obligation to produce such information in connection with this Litigation and of its intention to do so, subject to the protections of this Protective Order; (ii) inform the third party in writing of the third party's right within fourteen (14) days to seek further protection or other relief from the Court if, in good faith, it believes such information to be confidential under said obligation and either objects to the Party's production of such information or regards the provisions of this Protective Order to be inadequate; and (iii) seek the third party's consent to such disclosure if that third party does not plan to object. Thereafter, the Party shall refrain from producing such information for a period of fourteen (14) days in order to permit the third party an opportunity to seek relief from the Court, unless the third party earlier consents to disclosure. If the third party fails to seek such relief, the Party shall promptly produce the information in

question subject to the protections of this Protective Order, or alternatively, shall promptly seek to be relieved of this obligation or for clarification of this obligation by the Court.

XIV. Miscellaneous Provisions

75. Nothing in this Order or any action or agreement of a Party under this Order limits the Court's power to make any orders that may be appropriate with respect to the use and disclosure of any documents produced or use in discovery or at trial.

76. Nothing in this Protective Order shall abridge the right of any person to seek judicial review or to pursue other appropriate judicial action to seek a modification or amendment of this Protective Order.

77. In the event anyone shall violate or threaten to violate the terms of this Protective Order, the Designating Party may immediately apply to obtain injunctive relief against any person violating or threatening to violate any of the terms of this Protective Order, and in the event the Designating Party shall do so, the respondent person, subject to the provisions of this Protective Order, shall not employ as a defense thereto the claim that the Designating Party possesses an adequate remedy at law.

78. This Protective Order shall not be construed as waiving any right to assert a claim of privilege, relevance, or other grounds for not producing Discovery Material called for, and access to such Discovery Material shall be only as provided for by separate agreement of the Parties or by the Court.

79. This Protective Order may be amended without leave of the Court by agreement of Outside Counsel for the Parties in the form of a written stipulation filed with the Court. The Protective Order shall continue in force until amended or superseded by express order of the Court, and shall survive and remain in effect after the termination of this Litigation.

80. Notwithstanding any other provision in the Order, nothing in this Protective Order shall affect or modify Defendants' ability to review Plaintiffs' information and report such information to any applicable regulatory agencies.

81. This Order is entered based on the representations and agreements of the Parties and for the purpose of facilitating discovery. Nothing herein shall be construed or presented as a judicial determination that any documents or information designated as Confidential or Highly Confidential by counsel or the Parties is subject to protection until such time as the Court may rule on a specific document or issue.

IT IS SO ORDERED.

By: _____
HON. JERRY GARGUILO

Dated: 1/29/19

HON. JERRY GARGUILO

GRANTED
JAN 29 2019
Judith A. Pascale
CLERK OF SUFFOLK COUNTY

EXHIBIT A TO STIPULATED PROTECTIVE ORDER
ACKNOWLEDGMENT AND AGREEMENT
TO BE BOUND BY PROTECTIVE ORDER

The undersigned agrees:

I declare under penalty of perjury that I have read in its entirety and understand the Protective Order that was issued by the Supreme Court of the State of New York, County of Suffolk, on _____, 2019 in *In Re Opioid Litigation*, Index No. 400000/2017 E (the "Protective Order").

I agree to comply with and to be bound by all the terms of the Protective Order, and I understand and acknowledge that failure to so comply could expose me to sanctions and punishment in the nature of contempt. I solemnly promise that I will not disclose in any manner any information or item that is subject to the Protective Order to any person or entity except in strict compliance with the provisions of the Protective Order.

I further agree to submit to the jurisdiction of the Supreme Court of the State of New York, County of Suffolk for the purposes of enforcing terms of the Protective Order, even if such enforcement proceedings occur after termination of these proceedings.

Date:_____

City & State Where Signed:_____

Printed Name:_____

Signature:_____

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**MDL 2804**
	)	**Case No. 1:17-md-2804**
THIS DOCUMENT RELATES TO:	)	**Judge Dan Aaron Polster**
Track Three Cases	)	**ORDER**

Before the Court is Pharmacy Defendants' Motion to Compel Limited Additional Data from the Ohio Board of Pharmacy's OARRS Database. Doc. #: 3364. For the reasons stated below, the Motion is **GRANTED**.

I. Background

In Track One-A of the MDL, defendant McKesson served a subpoena upon the Ohio Board of Pharmacy ("OBOP") seeking production of ***all*** dispensing data from OBOP's database known as the Ohio Automated Rx Reporting System ("OARRS").[1] OBOP refused to comply with the subpoena, so McKesson moved to compel. The Court denied the motion as overbroad, but suggested McKesson was entitled to ***some*** of the data it was seeking and directed the parties to try and work things out.[2] Ultimately, OBOP agreed to provide to defendants certain OARRS data statewide from 2008 to 2018. The chart on the following page shows which data fields OBOP agreed to produce.[3] (The blue highlighting is explained further below.)

[1] "OARRS consists of two databases: a patient database that contains records of all controlled substances dispensed to outpatients, and an ARCOS-like database that contains records of shipments of those medications by wholesalers and others. This motion concerns only the former." Motion at 3 (doc. #: 3364); *see* Response at 3 (doc. #: 3380).
[2] *See* Order at 2 (doc. #: 1292) ("Some access to the information contained in the OARRS database may be important for a full and complete understanding of the contours of liability in this litigation," but "McKesson's request must be tailored to include geographic and temporal restrictions. Nonproduction or redaction of certain data-fields might be appropriate as well. * * * McKesson and OBOP are directed to continue negotiating to appropriately limit the scope of the data produced by OBOP.").
[3] *See* Mot. at 4 (doc. #: 3364); Response at 12 n.5 (doc. #: 3380).

Data Field	Produced?
Date Prescription Filled	yes
Prescription Number	yes
Date Prescription Written	yes
Quantity	yes
Number of Refills	yes
Number of Days Supply	yes
NDC Code	yes
Payment Type	yes
Pharmacy Name	NO*
Pharmacy Address	NO
OBOP Pharmacy Number	NO
OBOP Pharmacy Business Activity Codes and Subcodes	yes
Physician Name	NO*
Physician Address	NO
OBOP Physician Number	NO
OBOP Physician Business Activity Codes and Subcodes	yes
Patient Name	NO*
Patient Sex	yes
Patient Address	NO
Patient Age	yes
Patient Condition	NO

*Unique ID number supplied instead

At the time OBOP produced this data during Track One-A, the only claims pending against the Pharmacy Defendants related to their *distribution* of opioids to their own stores. Now, Plaintiffs in Track Three also assert claims related to the Pharmacy Defendants' *dispensing*

practices.[4] Accordingly, in order to defend against these additional allegations, the Pharmacy Defendants have served a subpoena upon OBOP seeking additional OARRS data – specifically, the data fields highlighted above in blue.[5] Notably, the Pharmacy Defendants are *not* seeking information that identifies patients; rather, they seek information identifying doctors and pharmacies.

OBOP refused to comply with the subpoena, so the Pharmacy Defendants move to compel. OBOP argues the Court should deny the motion because the Pharmacy Defendants already have all the information they need to defend against the Plaintiffs' claims, and the data they seek is privileged under Ohio law.[6] For the reasons stated below, the Court finds OBOP's arguments unconvincing.

II. Analysis

a. Defendants' need for OARRS data

The Pharmacy Defendants explain the relevance of and their need for the additional OARRS data as follows:

> [A]ccording to the ARCOS data [obtained from the U.S. DEA], the Pharmacy Defendants make up just 58 percent of the dispensing market in [the Track Three plaintiff] counties between 2006 and 2014. The Pharmacy Defendants have no information about most of the prescribers, prescriptions, or dispensing practices associated with the pharmacies and other dispensers that make up the other 42 percent of the market. Those non-defendant dispensers received more than 71 million dosage units of opioids between 2006 and 2014, according to ARCOS data.

[4] As the Motion explains, after OBOP's production during Track One, the Plaintiffs amended their Complaints to add allegations based on the Pharmacies' dispensing conduct. In preparation for defending against those allegations, the Pharmacies served a subpoena seeking additional data from OBOP, and the Court granted the Pharmacies' motion to compel production of the data. Doc. #: 3168. The Court withdrew that Order as moot after the Sixth Circuit ordered the Court to strike the amendments in Track One. Doc. #: 3313. Thus, the current motion is the second time the Pharmacy Defendants have sought to compel OBOP to produce additional OARRS data.

[5] *See* Mot. at 10 (doc. #: 3364) ("All the Pharmacy Defendants ask is that the same [OARRS] data previously produced be updated and reproduced with the ***dispenser*** and ***prescriber*** fields included.").

[6] OBOP does not argue the Pharmacy Defendants have failed to demonstrate good cause for seeking the data.

> On June 10, the Pharmacy Defendants served a new subpoena on [OBOP] seeking, among other things, the limited additional OARRS data at issue here, i.e., data identifying the dispensers and prescribers associated with the millions of opioids prescriptions in Lake and Trumbull Counties that the Pharmacy Defendants did not fill.
>
> * * *
>
> [This] information is necessary to show widespread alternative causes of the alleged nuisance, e.g., the large number of "over-prescribers," "pill mills," and other dispensers Plaintiffs chose not to sue.
>
> * * *
>
> The OARRS data is also necessary to identify "doctor shoppers" in a de-identified fashion.
>
> * * *
>
> OARRS is the only dataset anywhere that allows the tracing of individuals across doctors and pharmacies. Therefore, it is the only dataset that allows the identification of doctor shoppers who sought pills from multiple places, as well as the over-prescribers who wrote those patients' prescriptions.

Mot. at 5-9 (doc. #: 3364); *see id.* at 9 (further explaining that the Pharmacy Defendants' own, different databases do not allow cross-referencing between them of patients or prescribers, or between other non-defendant dispensers).

OBOP responds that the data it already produced, including a unique identifier for each patient, physician, and pharmacy, sufficiently fulfills the Pharmacy Defendants' need to identify alternative causes of the alleged nuisance. But the Pharmacies aim to identify specific non-party pill mills and over-prescribers, with the goal of showing it was these other actors (and not the Pharmacy defendants) who caused any alleged public nuisance. The Pharmacies cannot make this showing with de-identified data. Put simply, the Pharmacies cannot pursue a potential defense without the actual identities contained in the OARRS data fields they seek.

OBOP further argues that, as a practical matter, if the Pharmacy Defendants receive the additional data they seek – which does *not* include patient names or addresses – the Defendants will nonetheless be able to identify each patient and all of her prescriptions. OBOP explains:

> For example, if Walgreens … was supplied with all information for a particular prescription that was filled at a Walgreens pharmacy – the drug prescribed, the date the prescription was written, the date the prescription was filled, quantity, number of refills, prescriber name, and specific pharmacy name and address at which the prescription was filled – Walgreens could locate that particular prescription within its records. Walgreens' records would necessarily include the patient name for the prescription, thus, revealing the identity of that patient. Walgreens would then know the unique identifying number, or hash, used for that patient in the Research Extraction.

Response at 11 (doc. #: 3380).

While this may be true, it ignores several facts. First, during a discovery conference, the Pharmacy Defendants agreed they will not do this, and even invited the Court to enter an order prohibiting it. The Defendants do not need to identify specific ***patients*** to assert their defense; they only need to identify the prescribers and pharmacies associated with a specific patient, which they can do utilizing OBOP's de-identified patient ID number. Accordingly, the Pharmacy Defendants are ordered not to use their own data to "reverse-engineer" patient-identifying information contained in the de-identified OARRS data they receive.

Second, all of the OARRS data will be subject to the numerous protective orders entered by the Court in this MDL, *see*, *e.g.*, doc. #: 2987 at 1 (listing all such orders), and the Pharmacy Defendants have explicitly recognized this. *See* Mot. at 6 (doc. #: 3364) ("The Pharmacy Defendants agree that [OBOP] may designate the production under the Court's existing HIPAA Protective Order."). Accordingly, the privacy concerns raised by OBOP are mitigated.

And third, as reflected in the other filings related to dispensing data (*see* doc. ##: 3084, 3149), the Pharmacy Defendants clearly take seriously the privacy of their patients. Indeed, the Pharmacy Defendants *already have* and are required to safeguard the precise types of data they now seek from OBOP. OBOP is rightly concerned about preserving the privacy of patient prescriptions, but that is exactly what the Pharmacy Defendants already do routinely regarding

prescriptions they fill themselves. Allowing the Pharmacy Defendants access to information regarding prescriptions filled at other pharmacies does not meaningfully increase the types and amounts of private information the Defendants already have.[7]

In sum, the undersigned is convinced that production of the requested OARRS data to the Pharmacy Defendants will not lead to actual invasions of patient privacy beyond that which patients already experience whenever they fill a prescription. The relevance of the data is clear and the Pharmacies' need for it outweighs any countervailing concerns.

b. Confidentiality and privilege

OBOP also objects that various federal and state statutes preclude production of the additional OARRS data. But these statutes are premised entirely on the concern that disclosure of data would allow identification of ***patients***. Because the Pharmacy Defendants are ***not*** seeking patient-identifying data (such as name or address), and given the conclusion above regarding the unlikelihood of invasion of patient privacy, these objections are also not well-taken.[8]

Moreover, the state and federal statutes cited by OBOP may inform, but do not limit, this Court's discretion regarding scope of discovery. The federal statute cited by OBOP contains an explicit exception that data may be produced pursuant to a court order. *See* 42 U.S.C § 290dd-2 (b)(2)(C) ("Whether or not the patient. . . gives written consent, the content of such record may be disclosed . . . [i]f authorized by an appropriate order of a court of competent jurisdiction . . . ."). The state statute, Ohio Rev. Code §4729.80, does not contain a similar exception, but it likewise

[7] OBOP asks the Court to order only a single attorney and a single consultant for each Pharmacy Defendant be permitted to access the data. Response at 18 (doc. #: 3380). Like their clients, the Pharmacies' counsel are experienced in handling and protecting sensitive information, and the Court will not impose the unnecessary and impractical limits OBOP requests.

[8] It is notable that, in related state-court opioid litigation, the State of New York has voluntarily agreed to produce to the Pharmacy Defendants the same pharmacy and prescriber fields from its analogous database; this suggests OBOP's concerns about privacy and statutory restrictions are overblown.

does not limit the scope of discovery.[9]

OBOP argues the Court should find the database is privileged within the meaning of Federal Rule of Evidence 501. *See* response at 5. OBOP is generally correct regarding application of state law privileges in federal cases based on diversity jurisdiction. But the general rules cited by OBOP do not end the analysis; OBOP must show a specific state law privilege exists that governs this precise issue. *See Cleveland Clinic Health Sys.-E. Region v. Innovative Placements, Inc.*, 283 F.R.D. 362, 365 (N.D. Ohio 2012) (citation omitted) (holding that a party claiming privilege has the burden of proving the privilege applies).

OBOP makes no argument for the application of any specific privilege, instead it merely suggests that Ohio statutes that address the *confidentiality* of the OARRS database create a privilege. But "[c]onfidentiality is not … the same as privilege." *Lawrence v. Aken*, 316 F. Supp. 2d 547, 554 (W.D. Mich. 2004) (rejecting privilege claim and finding confidentiality order sufficiently protects confidentiality interests embodied in state statute); *Wade v. Vabnick-Wener*, 922 F. Supp. 2d 679, 685 (W.D. Tenn. 2010) (citation omitted) ("The term 'privilege' is a specific and well-defined term in the legal community…. Had our legislature intended to enact a privilege, the General Assembly, being versed in the legal lexicon, likely would have used the precise term 'privilege.'"). Thus, state statutes providing for confidentiality "do not automatically imply the creation of evidentiary privileges binding on courts." *Seales v. Macomb Cty.*, 226 F.R.D. 572, 576 (E.D. Mich. 2005) ("Merely asserting that a state statute declares that the records in question are

[9] *See Doan v. Allstate Ins. Co.*, No. 5:07cv13957, 2009 WL 10680123, at *3 n.2 (E.D. Mich. May 14, 2009) ("Discovery in federal courts is generally governed by the Federal Rules of Civil Procedure regardless of whether federal jurisdiction is based on a federal question or diversity of citizenship."); *Everitt v. Brezzel*, 750 F. Supp. 1063, 1065-1066 (D. Colo. 1990) (same); *Sharon Steel Corp. v. Travelers Indem. Co.*, 26 F.R.D. 113, 116 (N.D. Ohio 1960) (granting a motion to compel production of general counsel's notes prepared in anticipation of trial under Fed. R. Civ. P. 34, despite a contrary state ruling, explaining: "we cannot afford to allow state court rulings to influence what we consider to be the proper interpretation of the federal rules concerning discovery"); *see also* 8 Fed. Prac. & Proc. Civ. §2005 (3rd ed. 2019) ("State law is of very little relevance to discovery in a federal action.").

confidential does not make out a sufficient claim that the records are privileged within the meaning of Fed. R. Civ. P. 26(b)(1) and Fed R. Evid. 501."). Furthermore, in the absence of any express statutory language or judicial interpretation creating an evidentiary privilege, courts in this Circuit decline to read a privilege into statutes. *See, e.g., id.* at 576 (granting in part a motion to compel over objection that state confidentiality statutes create a privilege over information sought); *Lawrence*, 316 F. Supp. 2d at 552 ("Where privileges have been extended, the text of a state rule normally makes explicit reference to privilege.").

OBOP fails to identify any Ohio law evincing a privilege prohibiting the production of this data. OBOP primarily relies on a case applying Ohio Rev. Code. § 2317.02, which is entitled "Privileged Communications and Acts" and expressly creates various testimonial privileges. *See Jewell v. Holzer Hosp. Found., Inc.*, 899 F.2d 1507, 1513 (6th Cir. 1990).[10] Unlike that statute, the provisions upon which OBOP relies do not contain any reference to privilege. If the General Assembly intended to create an evidentiary privilege, it easily could have done so in express terms, as it did in § 2317.02. Thus, the Court finds OBOP has not shown a state law privilege exists that protects the data from discovery. As previously stated, the Court's protective orders sufficiently address the confidentiality interests reflected in the state statutes.

III. Conclusion

Accordingly, the Pharmacy Defendants' motion to compel is **GRANTED**. OBOP shall promptly provide to the Pharmacy Defendants the same OARRS data it previously produced, but

[10] Like *Jewell*, nearly every case OBOP cites involved a state statute containing express language creating privileges. *See* response at 6 (doc. #: 3364) (citing *State Farm. Mut. Auto. Ins. Co. v. Elite Heath Ctrs., Inc.*, 399 F. Supp. 3d 708, 711 (E.D. Mich. 2019); *Babock & Wilcox Power Generation Group, Inc. v. Cormetech, Inc.*, 81 F. Supp. 3d 632, 640 (N.D. Ohio 2015); *Freudeman v. Landing of Canton*, No. 5:09cv00175, 2010 WL 2196460, at *11 (N.D. Ohio May 31, 2010)). OBOP mistakenly relies on one case that addressed the distinction it failed to make here – between privilege and confidentiality – and concluded a state confidentiality statute did not prohibit disclosure under Federal Rule of Evidence 501. *SBAV LP v. Porter Bancorp, Inc.*, No. 3:13cv00710, 2015 WL 1471020, at *5–8 (W.D. Ky. Mar. 31, 2015), *vacated as moot*, 2015 WL 8004502 (W.D. Ky. Dec. 1, 2015).

updated and with the pharmacy and prescriber fields included. Pharmacy Defendants shall ensure counsel for OBOP promptly receives a copy of this Ruling.

As before, the Court does not believe it is appropriate to, and will not, authorize immediate appeal of this *Discovery Ruling* pursuant to 28 U.S.C. §1292(b). *See* case no. 18-OP-45090, docket entry dated Mar. 17, 2020 (denying OBOP's motion to amend order to authorize an appeal).

IT IS SO ORDERED.

/s/ Dan Aaron Polster_July 24, 2020_
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE

OARRS

OHIO AUTOMATED RX REPORTING SYSTEM

2018 ANNUAL REPORT

STATE OF OHIO BOARD OF PHARMACY

Mike DeWine
Governor

Steven W. Schierholt, Esq.
Executive Director

www.pharmacy.ohio.gov

OHIO AUTOMATED RX REPORTING SYSTEM

What is OARRS?

To address the growing misuse and diversion of prescription drugs, the Ohio General Assembly adopted legislation in 2004 authorizing the State of Ohio Board of Pharmacy to create a Prescription Monitoring Program (PMP), known as the Ohio Automated Rx Reporting System (OARRS). Established in 2006, OARRS collects information on all outpatient prescriptions for controlled substances and two non-controlled substances (gabapentin and naltrexone) dispensed by Ohio-licensed pharmacies and personally furnished by Ohio prescribers. This data is reported every 24 hours and is maintained in a secure database. Drug wholesalers and manufacturers are also required to submit information monthly on all controlled substances and gabapentin sold to an Ohio licensed pharmacy or prescriber.

OARRS serves multiple functions, including: patient care tool; drug epidemic early warning system; and drug diversion and insurance fraud investigative tool. As the only statewide electronic database that stores all controlled substance dispensing and personal furnishing information, OARRS helps prescribers and pharmacists avoid potentially life-threatening drug interactions as well as identify individuals fraudulently obtaining controlled substances from multiple healthcare providers, a practice commonly referred to as “doctor shopping.”

It can also be used by professional licensing boards to identify or investigate clinicians with patterns of inappropriate prescribing and dispensing, assist law enforcement in cases of controlled substance diversion, provide drug court judges and court personnel with critical information regarding a participant’s use of controlled substance medications, and provide hospital peer review committees information on a prescriber who is subject to the committee’s evaluation, supervision, or discipline.

To learn more about OARRS, please visit: **www.pharmacy.ohio.gov/oarrs**.

Submission of this Report

Pursuant to section 4729.85 of the Revised Code, the State of Ohio Board of Pharmacy respectfully submits the following report on opioid pain relievers and other controlled substances dispensed by Ohio pharmacies or personally furnished by prescribers. This report will be disseminated to the Governor, the President of the Senate, the Speaker of the House of Representatives, the Attorney General, the chairpersons of the standing committees of the House of Representatives and the Senate that are primarily responsible for considering health and human services issues, the Department of Public Safety, the State Dental Board, the Board of Nursing, the State Vision Professionals Board, the State Medical Board, and the State Veterinary Medical Licensing Board.

STATE OF OHIO
BOARD OF PHARMACY

Dear Governor DeWine and Members of the Ohio General Assembly,

On behalf of the members of the State of Ohio Board of Pharmacy, I am pleased to provide the 2018 Ohio Automated Rx Reporting System (OARRS) Annual Report. The report demonstrates Ohio's continued progress in promoting the safe prescribing of opioids and benzodiazepines.

OARRS is a vital tool in Ohio's efforts to combat prescription drug misuse and abuse. Use of the system continues to increase at record rates thanks to the Board's efforts to promote the integration of OARRS into electronic health records and pharmacy dispensing systems. Since implementing the first statewide integration program in the nation, we have onboarded a significant number of health systems, clinics and pharmacies throughout the state. Because of these efforts, more than 41,000 pharmacists and prescribers have instant access to OARRS as part of their workflow.

Data from OARRS also plays an invaluable role in protecting the health and well-being of Ohioans, including:

- **Identifying aberrant healthcare providers:** Dedicated Board staff use OARRS data to identify and investigate healthcare professionals who may be engaged in criminal activity. Such efforts have led to criminal indictments, convictions and administrative actions.

- **Identifying those who may need help:** The Board recently implemented a pre-criminal intervention program that uses OARRS data to identify individuals who may be exhibiting signs of addiction. Once identified, specially trained Board agents engage these individuals to connect them with appropriate drug treatment and other support services.

- **Driving policy decisions:** Through collaborative efforts with other state agencies, OARRS data is used to develop new policies and initiatives. For example, data from the system was used to develop common-sense prescribing limits as part Ohio's new rules governing the use of opioids for the treatment of acute pain.

The Board recognizes that it is important to provide students in the healthcare field with tools to reinforce best practices. To that end, the Board launched OARRS Academy in September 2018. OARRS Academy is a training program designed to simulate the use of OARRS. The program comes pre-loaded with data for a variety of sample patients and allows for the creation of additional sample patients. It is available at no cost to all Ohio colleges and universities engaged in the training of pharmacists and prescribers. For more information on OARRS Academy, visit: **www.oarrsacademy.ohio.gov**.

OARRS ACADEMY
EDUCATION FOR Rx SAFETY

77 South High Street, 17th Floor, Columbus, Ohio 43215

T: (614) 466.4143 | **F:** (614) 752.4836 | **contact@pharmacy.ohio.gov** | **www.pharmacy.ohio.gov**

New for the 2018 Annual Report is information on the dispensing of controlled substance stimulants. Examples of such stimulants include amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®). Since 2012, the total doses of controlled substance stimulants dispensed to Ohio patients increased by 20 percent. The Board will continue to closely monitor this trend.

As the pages of this report will attest, Ohio is making significant strides in its efforts to promote a measured approach to the prescribing of opioids and benzodiazepines. This progress would not be possible without the support of our partners at all levels, including Ohio's healthcare provider community.

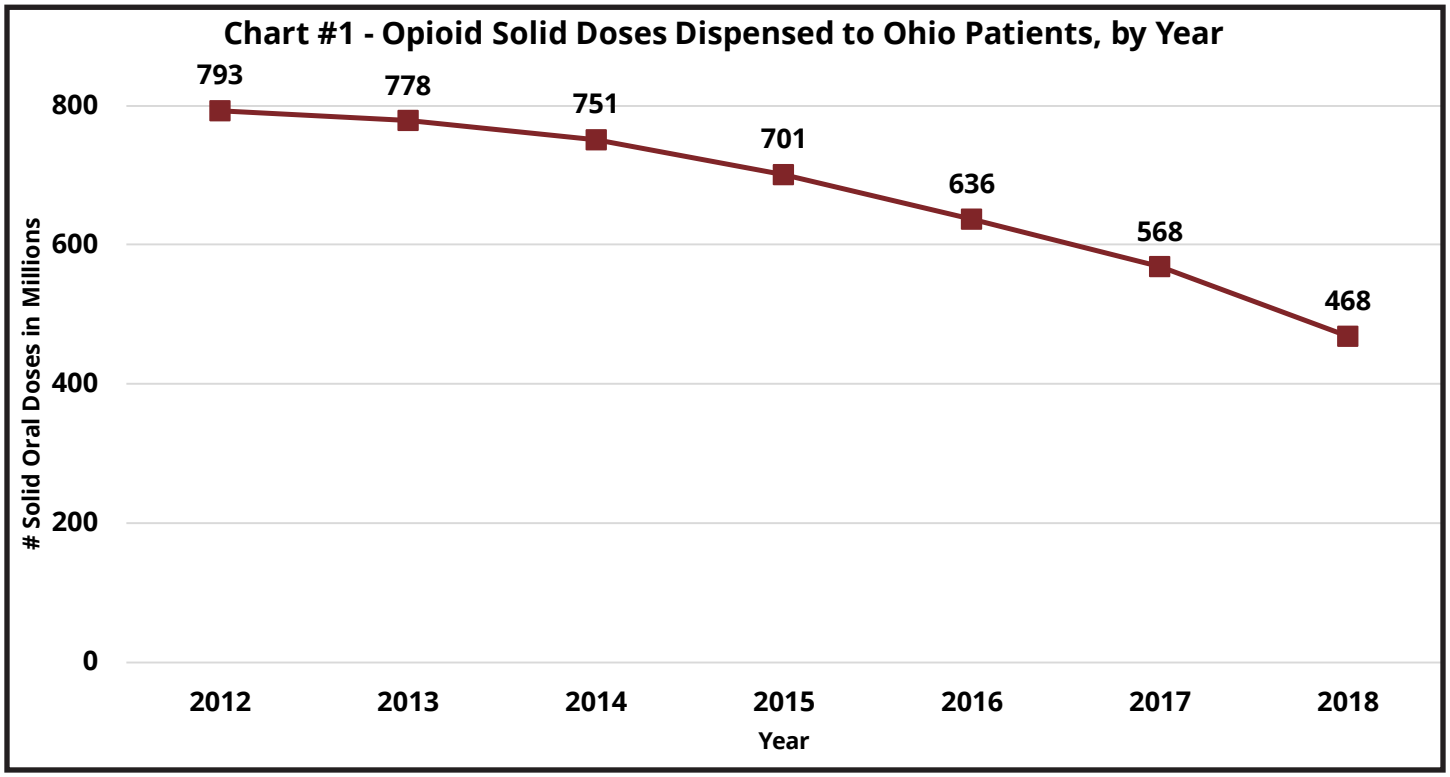
On behalf of the members of the State of Ohio Board of Pharmacy, I thank you for your leadership and ongoing support of OARRS. If you have any questions regarding the work of the Board, please do not hesitate to contact my office by phone (614-466-4143) or by e-mail: **contact@pharmacy.ohio.gov**.

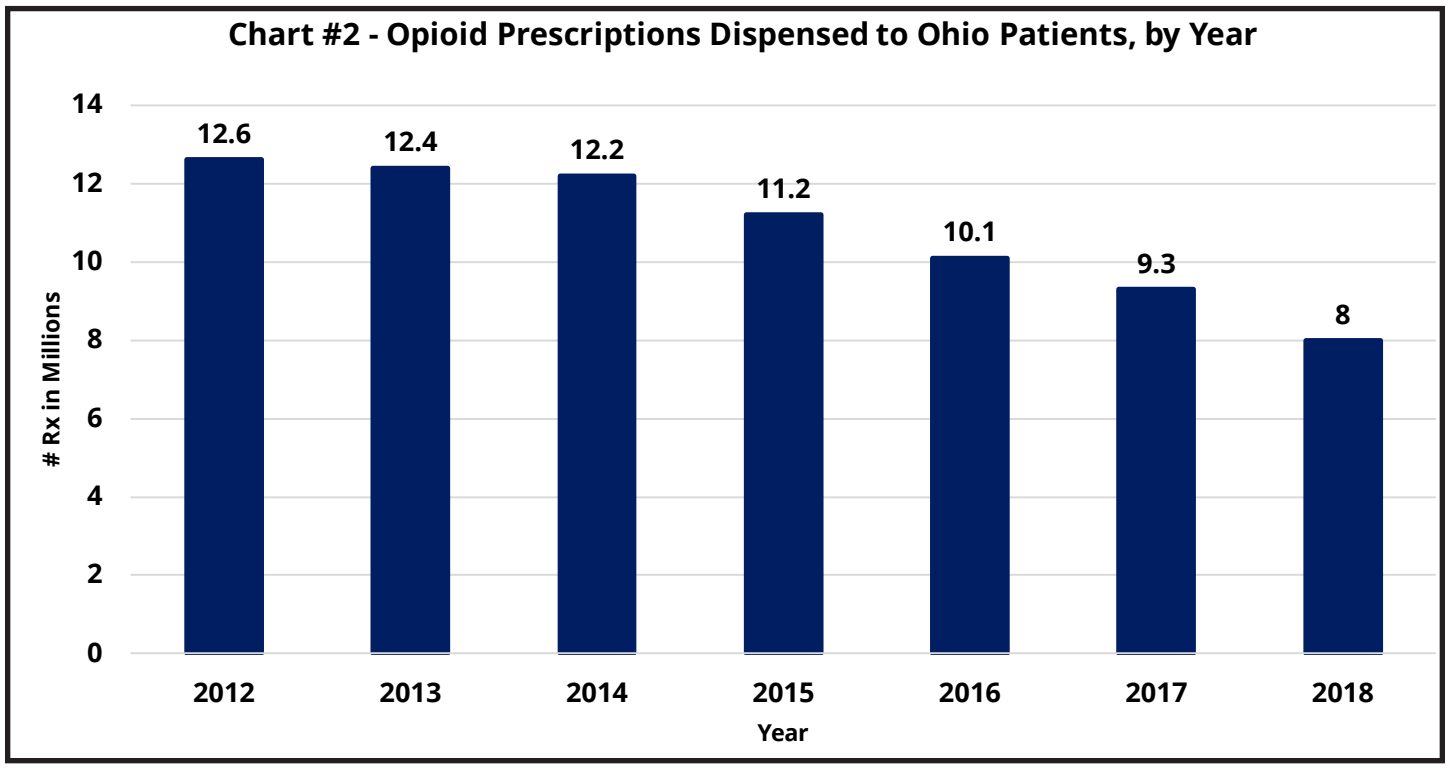
Sincerely,

Steven W. Schierholt, Esq.
Executive Director
State of Ohio Board of Pharmacy

Section 1: Opioids Dispensed to Ohio Patients

In 2018, the number of opioid doses* and prescriptions dispensed to Ohio patients continued to decrease. Total doses of opioids decreased from a high of 793 million in 2012 to 468 million in 2018, a 41 percent decrease (Chart #1). The total number of opioid prescriptions decreased by 4.6 million between 2012 and 2018, a 37 percent decrease (Chart #2).





*Solid dosage units only (eg. tablets, capsules and patches). Liquids and powders are not included.

Pursuant to section 4729.85 of the Revised Code, the Board is required to report opioid prescriptions dispensed by pharmacies to Ohio patients (see Table #1), including all of the following information:

- The number of prescribers who issued prescriptions for opioid pain relievers;
- The number of patients to whom opioid pain relievers were dispensed;
- The average quantity of opioid pain relievers dispensed per prescription;
- The average daily morphine equivalent dose (MED) of the opioid pain relievers dispensed per prescription.

Table #1 - Opioids* Dispensed to Ohio Patients, by Year

Year	No. of Prescribers	No. of Patients	Average Quantity per Prescription	Average Daily MED per Prescription
2010	55,895	2,733,066	64.37	53.35
2011	66,554	2,761,707	64.55	48.58
2012	66,649	3,053,090	65.38	47.89
2013	65,452	2,686,169	65.20	46.66
2014	63,178	2,650,078	64.15	45.34
2015	57,673	2,615,768	64.59	44.92
2016	56,287	2,359,175	65.48	44.43
2017	55,107	1,998,846	66.48	43.23
2018	56,221	1,850,561	63.43	39.23

*Buprenorphine used to treat opioid dependence or addiction is excluded.

WHAT IS A MORPHINE EQUIVALENT DOSE?

A morphine equivalent dose (MED) is the total amount of opioid medications, converted to a common unit (milligrams of morphine), that a patient currently has access to based on the information reported by prescribers and pharmacies to OARRS. Morphine is widely regarded as the "standard" for the treatment of moderate to severe pain and is commonly used as a reference point. As MED increases, the likelihood of an adverse event increases, therefore identifying at-risk patients is a crucial first step towards improving patient safety. OARRS utilizes opioid conversions created by the US Centers for Disease Control and Prevention (CDC).

Ohio's Rules on Prescription Opioids for Acute Pain generally limit an opioid prescription for acute pain to an average of 30 mg MED per day. For more information on the rules, visit: **www.pharmacy.ohio.gov/acutelimits**.

Ohio prescribers also need to follow new regulations when prescribing opioids for the treatment of long-term pain (lasting 12 weeks or more) and subacute pain (lasting between six and 12 weeks). The new rules establish MED check points to ensure appropriate prescribing. For more information on the rules, visit: **www.pharmacy.ohio.gov/chronicpain**.

Section 2: Opioids Personally Furnished by Ohio Prescribers

Pursuant to section 4729.85 of the Revised Code, the Board is required to report on the number of opioid pain relievers that have been personally furnished to a patient by an Ohio prescriber (see Table #2), including all of the following information:

- The number of prescribers who personally furnished opioid pain relievers;
- The number of patients to whom the opioid pain relievers were personally furnished;
- The average quantity of the opioid pain relievers that were furnished at one time;
- The average daily morphine equivalent dose (MED) of the opioid pain relievers that were furnished at one time.

Table #2 - Opioids* Personally Furnished by Ohio Prescribers, by Year

Year	No. of Prescribers	No. of Patients	Average Quantity Per Instance	Average Daily MED per Instance
2010**	13	1,394	306.46	114.04
2011**	93	735	69.70	35.32
2012	198	2,215	15.02	19.92
2013	180	2,761	9.15	17.95
2014	192	2,085	10.11	19.64
2015	235	1,877	17.41	31.20
2016	113	1,465	28.26	29.29
2017	34	888	24.67	25.29
2018	31	970	15.71	19.49

*Buprenorphine used to treat opioid dependence or addiction is excluded.

**Mandatory reporting to OARRS by prescribers who personally furnish controlled substances went into effect on May 20, 2011.

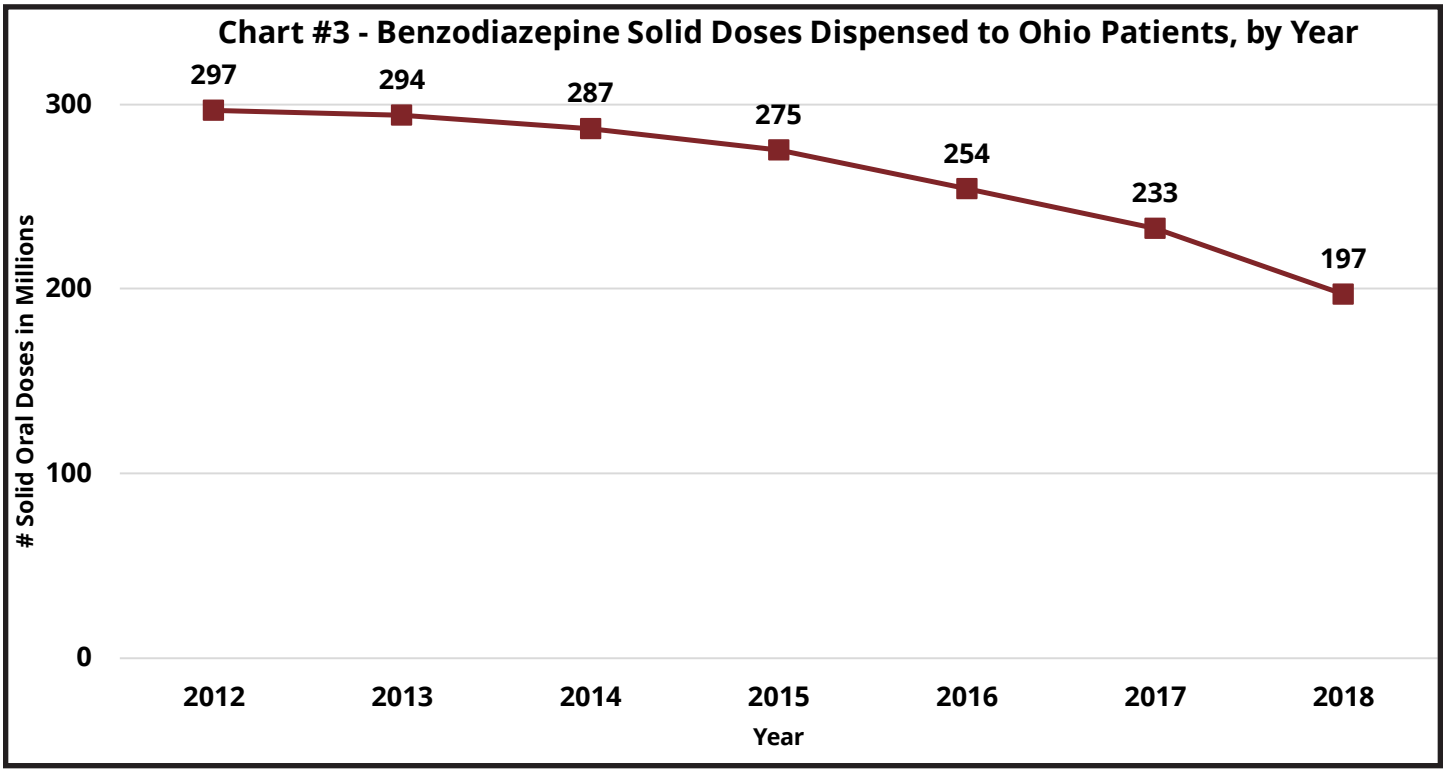
WHAT IS THE DIFFERENCE BETWEEN DISPENSING AND PERSONALLY FURNISHING?

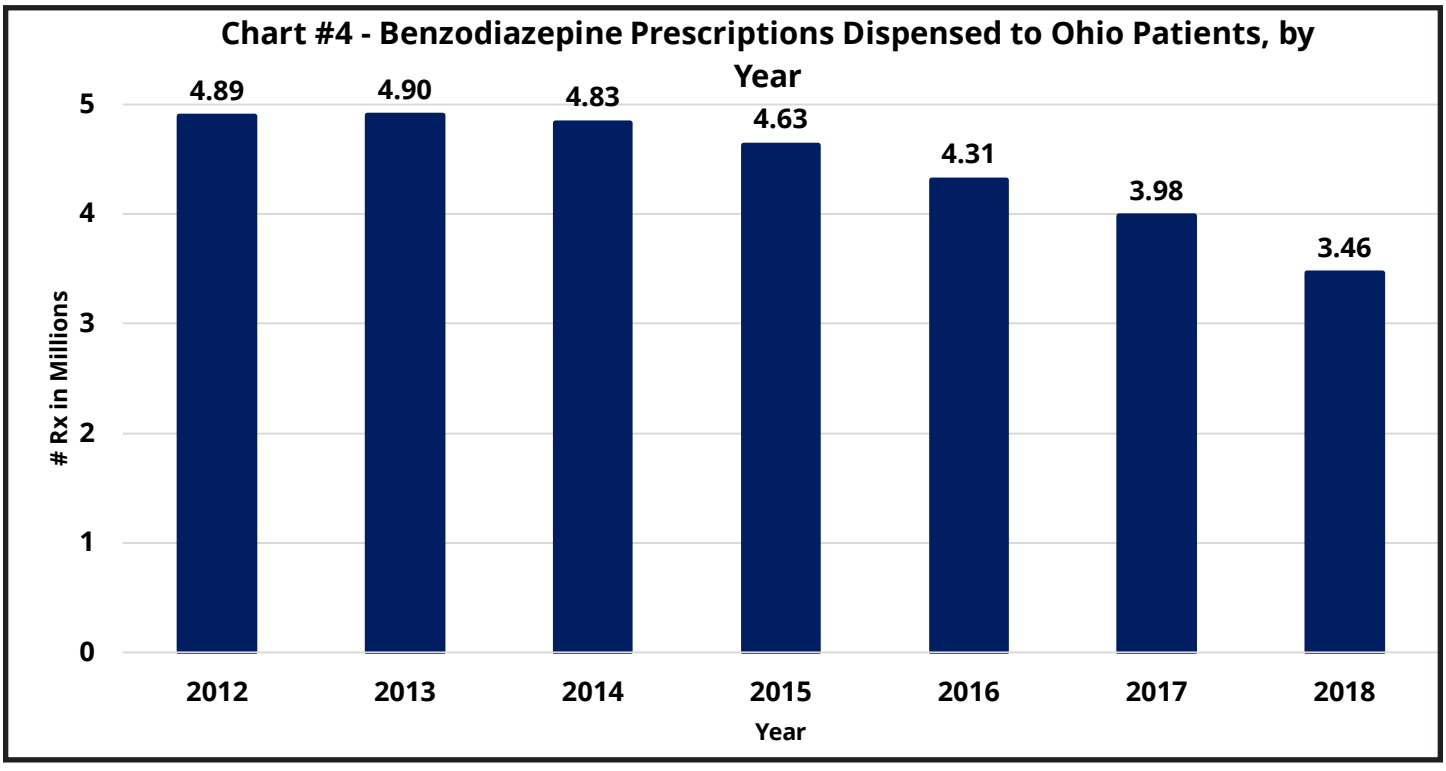
Dispensing is defined by law as the distribution of drugs by a pharmacist pursuant to a valid prescription from a prescriber. Personally furnishing is defined as the distribution of drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting. Except in a limited number of circumstances, prescribers are not permitted to personally furnish a controlled substance in excess of a seventy-two-hour supply (ORC 4729.291 - Effective May 20, 2011).

Ohio prescribers who personally furnish controlled substances or gabapentin from their offices are required to report those medications to OARRS within 24 hours (ORC 4729.79). This also includes any samples.

Section 3: Benzodiazepines Dispensed to Ohio Patients

In 2018, the number of benzodiazepine doses* and prescriptions dispensed to Ohio patients continued to decrease. Total doses of benzodiazepines decreased from a high of 297 million in 2012 to 197 million in 2018, a 34 percent decrease (Chart #3). The total number of benzodiazepine prescriptions decreased by 1.43 million between 2012 and 2018, a 29 percent decrease (Chart #4).

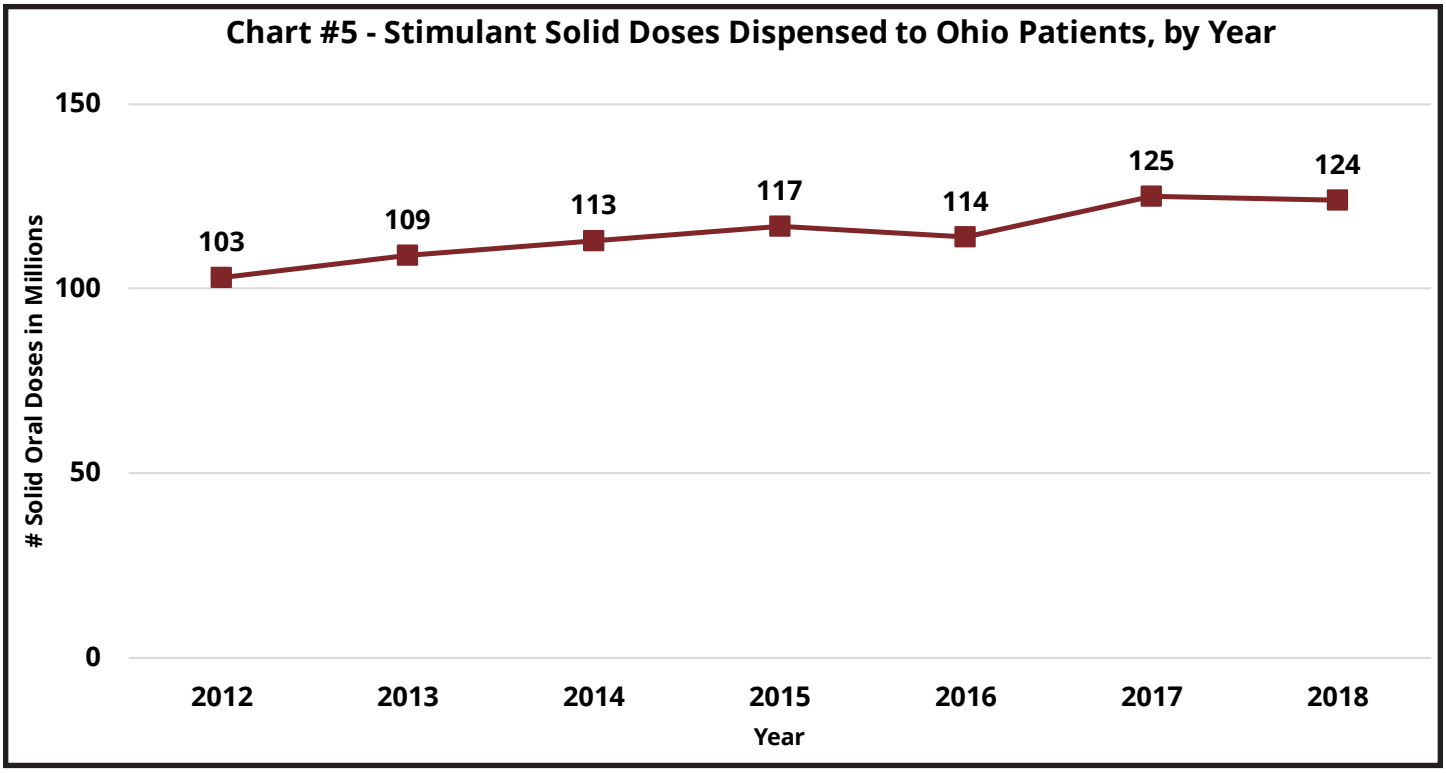


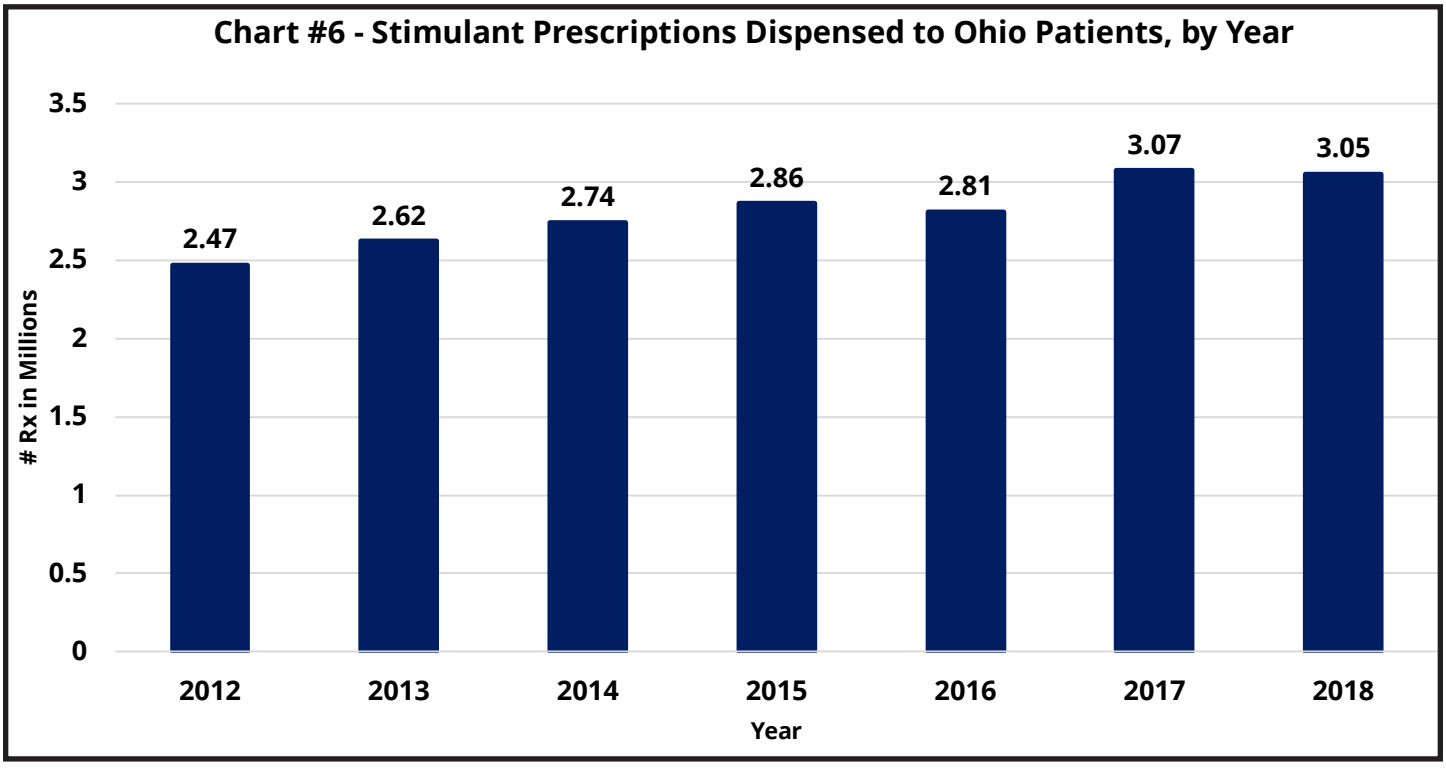


*Solid dosage units only (eg. tablets, capsules and patches). Liquids and powders are not included.

Section 4: Controlled Substance Stimulants Dispensed to Ohio Patients

In 2018, the number of stimulant doses* and prescriptions dispensed to Ohio patients decreased as compared to 2017. However, the total doses of stimulants increased by 20 percent between 2012 and 2018 (Chart #5). The total number of stimulant prescriptions also increased by 578,461 between 2012 and 2018, a 24 percent increase (Chart #6).

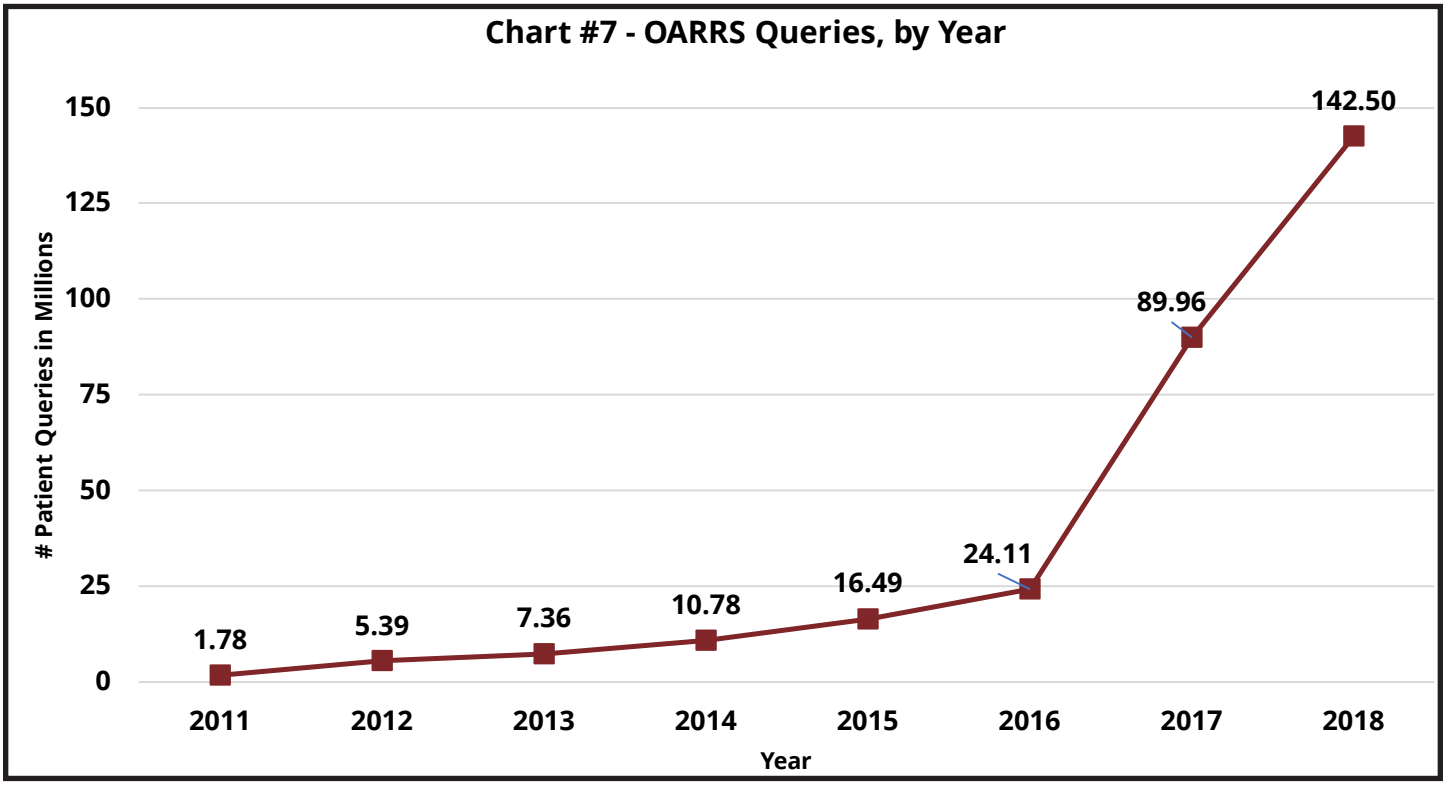


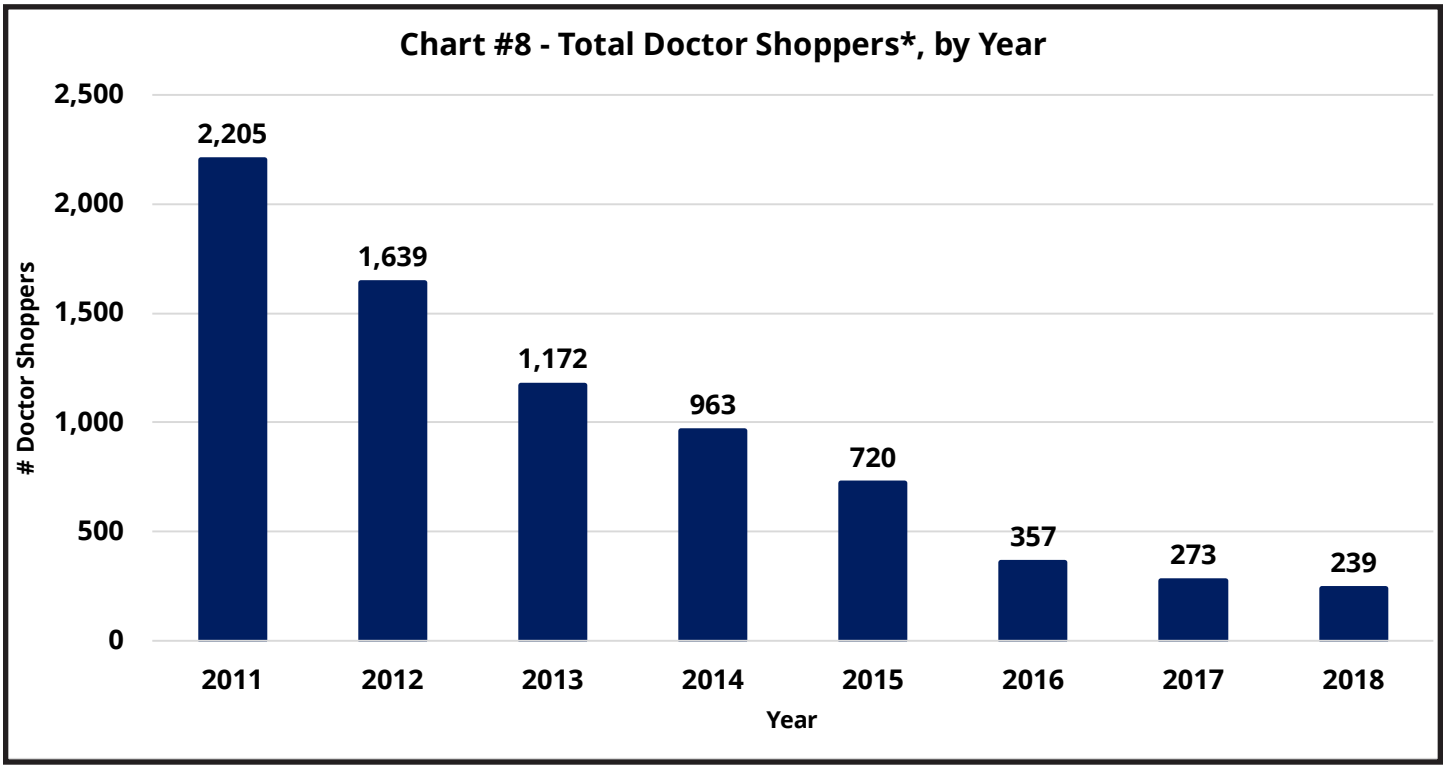


*Solid dosage units only (eg. tablets, capsules and patches). Liquids and powders are not included.

Section 5: OARRS Usage and Doctor Shoppers

The number of patient queries in OARRS increased from 1.78 million in 2011 to 142.50 million in 2018, an increase of more than 7,900 percent (see Chart #7). Conversely, the number of individuals who see multiple prescribers in order to obtain controlled substances illicitly (commonly referred to as "doctor shopping") decreased from 2,205 in 2011 to 239 in 2018, a decrease of 89 percent (see Chart #8).





*In this chart, a doctor shopper is defined as an individual receiving a prescription for a controlled substance from five or more prescribers in one calendar month.

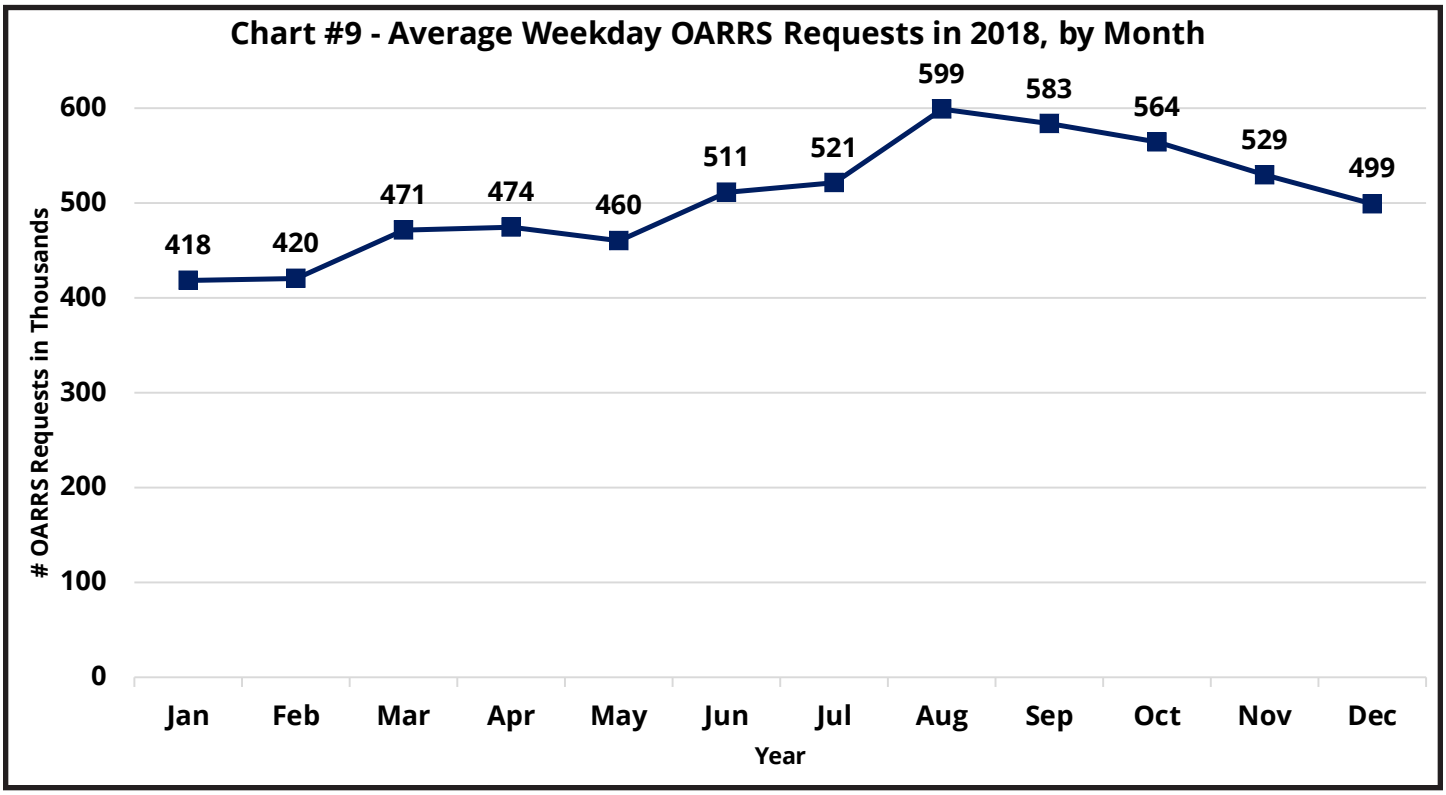
Section 6: OARRS Integration

In October 2015, Ohio became the first state in the country to offer statewide integration directly into electronic medical records and pharmacy dispensing systems. As a result of this initiative, more than 41,000 Ohio prescribers and pharmacists were able to immediately access OARRS within their clinical workflow in 2018 (see Table #3).

Table #3 - Ohio OARRS Users with Integrated Access in 2018, by User Type

User Type	Integrated Access
Prescriber	36,900
Pharmacist	4,162
Total	**41,062**

Integration has dramatically increased the average number of daily OARRS requests by healthcare providers. In 2018, the average number of OARRS requests per weekday exceeded 500,000 for the first time on record (see Chart #9).



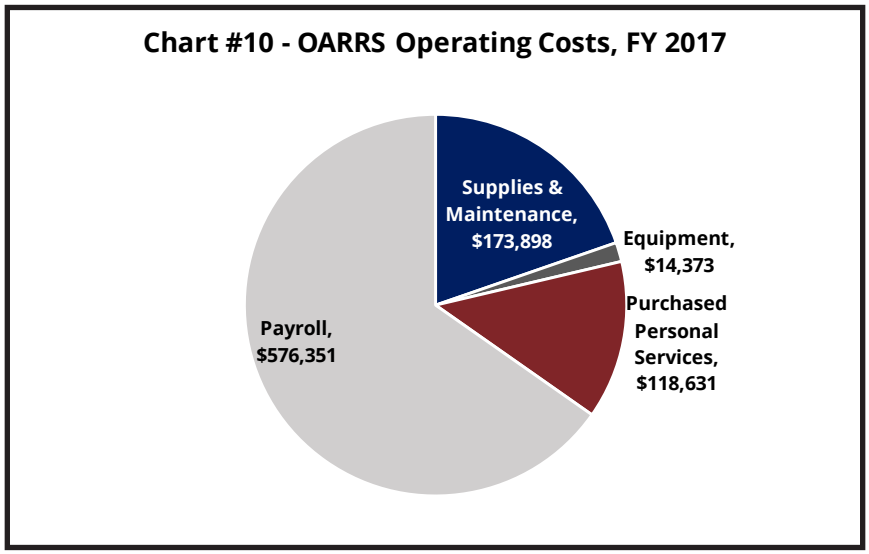
REQUIRED USE OF OARRS

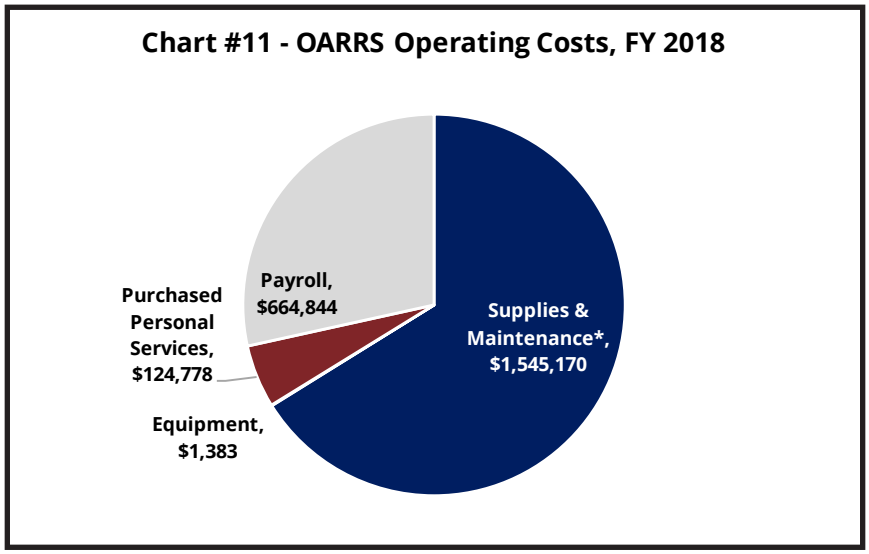
Ohio laws and rules require the use of OARRS by prescribers and pharmacists. For more information on the requirements for checking OARRS, visit: **www.pharmacy.ohio.gov/check**.

Section 7: Biennial Report

Pursuant to section 4729.85 of the Revised Code, the State of Ohio Board of Pharmacy submits the following biennial report that includes all of the following:

(1) The cost to the state of establishing and maintaining OARRS:





*Includes OARRS integration costs.

(2) The board's effectiveness in providing information from the database:

In 2018, OARRS automatically responded to 99.5% of the user requests for OARRS reports. The remaining reports (a half of a percent) required manual processing by Board of Pharmacy staff.

(3) The board's timeliness in transmitting information from the database:

In 2018, the average processing time to transmit an OARRS patient report was 0.1593 seconds.

The State of Ohio Board of Pharmacy is committed to protecting the health and safety of all Ohioans through the administration and enforcement of laws governing the legal distribution of dangerous drugs and the practice of pharmacy. Should you need any assistance or additional information, please do not hesitate to contact the Board.

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